

**DECLARATION OF CONFORMITY (EN)
КЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ (BG)
IZJAVA O SUKLADNOSTI (HR)
PROHLÁŠENÍ O SHODĚ (CS)
OVERENSSTEMMELSESERKLÆRING (DA)**



REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON MEDICAL DEVICES
РЕГЛАМЕНТ (ЕС) 2017/745 НА ЕВРОПЕЙСКИЯ ПАРЛАМЕНТ И НА СЪВЕТА ЗА МЕДИЦИНСКИТЕ ИЗДЕЛИЯ
UREDBA (EU) 2017/745 EUROPSKOG PARLAMENTA I VIJEĆA O MEDICINSKIM PROIZVODIMA
NAŘÍZENÍ EVROPSKÉHO PARLAMENTU A RADY (EU) 2017/745 O ZDRAVOTNICKÝCH PROSTŘEDCÍCH
EUROPA-PARLAMENTETS OG RÅDETS FORORDNING (EU) 2017/745 OM MEDICINSK Udstyr

Manufacturer: LM-Instruments Oy
Производител: SRN: FI-MF-000006705
Proizvođač: Norrbyn rantatie 8
Výrobce: 21600 Parainen
Producent: Finland
Tel. +358 2 4546 400

This declaration of conformity is under the sole responsibility of LM-Instruments Oy. Herewith we declare products listed in the appendix A comply with the regulations (EU) 2017/745 for medical devices by application of harmonized standards EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021 and EN ISO 15223-1:2021. The products are classified as Medical Devices, Class I.

Настоящата декларация за съответствие е под изключителната отговорност на LM-Instruments Oy. С настоящото декларираме, че продуктите, изброени в приложение А, отговарят на Регламент (ЕС) 2017/745 за медицинските изделия чрез прилагане на хармонизирани стандарти БДС EN ISO 13485:2016, БДС EN ISO 14971:2019, БДС EN ISO 17664-1:2021 и БДС EN ISO 15223 -1:2021. Продуктите са класифицирани като медицински изделия от клас I.

Ova izjava o sukladnosti pod isključivom je odgovornošću društva LM-Instruments Oy. Ovime izjavljujemo da su proizvodi navedeni u prilogu A sukladni s uredbom (EU) 2017/745 o medicinskim proizvodima, uz primjenu usklađenih normi EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021 i EN ISO 15223-1:2021. Proizvodi se mogu svrstati u medicinske proizvode klase I.

Za toto prohlášení o shodě nese výhradní odpovědnost společnost LM-Instruments Oy. Tímto prohlašujeme, že produkty uvedené v příloze A splňují předpisy (EU) 2017/745 pro zdravotnické prostředky s využitím harmonizovaných norem EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021 a EN ISO 15223-1:2021. Tyto produkty jsou klasifikovány jako zdravotnické prostředky třídy I.

Denne overensstemmelseserklæring er udelukkende LM-Instruments Oy's ansvar. Hermed erklærer vi, at de produkter, der er anført i bilag A, er i overensstemmelse med forordning (EU) 2017/745 om medicinsk udstyr ved anvendelse af de harmoniserede standarder EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021 og EN ISO 15223-1:2021. Produkterne er klassificeret som medicinsk udstyr, Klasse I.

**CONFORMITEITSVERKLARING (NL)
VASTAVUSDEKLARATSIOON (ET)
VAATIMUSTENMUKAISUUSVAKUUTUS (FI)
DÉCLARATION DE CONFORMITÉ (FR)
KONFORMITÄTSERKLÄRUNG (DE)**

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VERORDENING (EU) 2017/745 VAN HET EUROPEES PARLEMENT EN DE RAAD BETREFFENDE MEDISCHE HULPMIDDELEN

EUROOPA PARLAMENDI JA NÕUKOGU MEDITSIIINISEADMETE MÄÄRUS (EL) 2017/745

EUROOPAN PARLAMENTIN JA NEUVOSTON ASETUS (EU) 2017/745 LÄÄKINNÄLLISISTÄ LAITTEISTA

REGLEMENT (UE) 2017/745 DU PARLEMENT EUROPEEN ET DU CONSEIL RELATIF AUX DISPOSITIFS MEDICAUX

VERORDNUNG (EU) 2017/745 DES EUROPÄISCHEN PARLAMENTS UND DES RATES ÜBER MEDIZINPRODUKTE

Fabrikant: LM-Instruments Oy
Tootja: SRN: FI-MF-000006705
Valmistaja: Norrbyn rantatie 8
Fabricant: 21600 Parainen
Hersteller: Finland
Tel. +358 2 4546 400

Deze conformiteitsverklaring valt onder de uitsluitende verantwoordelijkheid van LM-Instruments Oy. We verklaren hierbij dat de producten die in bijlage A worden vermeld aan de Verordening (EU) 2017/745 betreffende medische hulpmiddelen voldoen door de toepassing van de geharmoniseerde normen EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021 en EN ISO 15223-1:2021. De producten zijn geclassificeerd als medische hulpmiddelen van klasse I.

See vastavusdeklaratsioon kehtib LM-Instruments Oy ainuvastutusel. Käesolevaga kinnitame, et lisas A loetletud tooted vastavad meditsiiniseadmeid käsitlevale määrusele (EL) 2017/745, kohaldades harmoneeritud standardeid EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021 ja EN ISO 15223-1:2021. Tooted on klassifitseeritud meditsiiniseadmetena, klass I.

Tämä vaatimustenmukaisuusvakuutus annetaan LM-Instruments Oy:n yksinomaisella vastuulla. Vakuutamme täten, että liitteessä A luetellut tuotteet ovat lääkinnällisiä laitteita koskevan asetuksen (EU) 2017/745 vaatimusten mukaisia sovellettaessa harmonisoituja standardeja EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021 ja EN ISO 15223-1:2021. Nämä tuotteet on luokiteltu luokan I lääkinnällisiksi laitteiksi.

Cette déclaration de conformité est sous la seule responsabilité de LM-Instruments Oy. Par la présente, nous déclarons que les produits énumérés dans l'annexe A sont conformes au règlement (UE) 2017/745 relatif aux dispositifs médicaux en application des normes harmonisées EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021 et EN ISO 15223-1:2021. Les produits sont considérés comme étant des dispositifs médicaux de classe I.

Diese Konformitätserklärung unterliegt der alleinigen Verantwortung von LM-Instruments Oy. Hiermit erklären wir, dass die in Anhang A aufgeführten Produkte den Verordnungen (EU) 2017/745 für Medizinprodukte durch Anwendung der abgestimmten Normen EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021 und EN ISO 15223-1:2021 entsprechen. Die Produkte sind als Medizinprodukte der Klasse I klassifiziert.

**ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ (EL)
MEGFELELŐSÉGI NYILATKOZAT (HU)
DICHIARAZIONE DI CONFORMITÀ (IT)
ATBILSTĪBAS DEKLARĀCIJA (LV)
ATITIKTIES DEKLARACIJA (LT)**

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ΚΑΝΟΝΙΣΜΟΣ (ΕΕ) 2017/745 ΤΟΥ ΕΥΡΩΠΑΪΚΟΥ ΚΟΙΝΟΒΟΥΛΙΟΥ ΚΑΙ ΤΟΥ ΣΥΜΒΟΥΛΙΟΥ ΓΙΑ ΤΑ ΙΑΤΡΟΤΕΧΝΟΛΟΓΙΚΑ ΠΡΟΪΟΝΤΑ

AZ EURÓPAI PARLAMENT ÉS TANÁCS ORVOSTECHNIKAI ESZKÖZÖKRE VONATKOZÓ (EU) 2017/745-ÖS RENDELETE

**REGOLAMENTO (UE) 2017/745 DEL PARLAMENTO EUROPEO E DEL CONSIGLIO SUI DISPOSITIVI MEDICI
EIROPAS PARLAMENTA UN PADOMES REGULA (ES) 2017/745, KAS ATTIECAS UZ MEDICĪNISKĀM IERĪCĒM
EUROPOS PARLAMENTO IR TARYBOS REGLAMENTAS (ES) 2017/745 DĖL MEDICINOS PRIEMONIŲ**

Κατασκευαστής: LM-Instruments Oy
Gyártó: SRN: FI-MF-000006705
Produttore: Norrbyn rantatie 8
Ražotājs: 21600 Parainen
Gamintojas: Finland
Tel. +358 2 4546 400

Η παρούσα δήλωση συμμόρφωσης υπόκειται στην αποκλειστική ευθύνη της LM-Instruments Oy. Δια του παρόντος, δηλώνουμε ότι τα προϊόντα που αναφέρονται στο παράρτημα Α συμμορφώνονται με τους κανονισμούς (ΕΕ) 2017/745 για τα ιατροτεχνολογικά προϊόντα με την εφαρμογή των εναρμονισμένων προτύπων EN ISO 13485: 2016, EN ISO 14971: 2019, EN ISO 17664-1: 2021 και EN ISO 15223 -1: 2021. Τα προϊόντα ταξινομούνται ως Ιατροτεχνολογικά προϊόντα, Κατηγορίας Ι.

Ez a megfelelőségi nyilatkozat az LM-Instruments Oy kizárólagos felelőssége alá tartozik. Kijelentjük, hogy az EN ISO 13485:2016, az EN ISO 14971:2019, az EN ISO 17664-1:2021 és az EN ISO 15223-1:2021 harmonizált szabvány alkalmazásával az A függelékben felsorolt termékek megfelelnek az orvostechikai eszközökről szóló (EU) 2017/745 rendeletnek. A termékek I. osztályú orvostechikai eszköz minősítésűek.

Questa dichiarazione di conformità è sotto la sola responsabilità di LM-Instruments Oy. Con la presente dichiariamo che i prodotti elencati nell'appendice A sono conformi ai regolamenti (UE) 2017/745 per i dispositivi medici in applicazione degli standard armonizzati EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021 e EN ISO 15223-1:2021. I prodotti sono classificati come Dispositivi medici, Classe I.

Par šo atbilstības deklarāciju atbildīgs ir tikai uzņēmums LM-Instruments Oy. Ar šo mēs apliecinām, ka A pielikumā norādītie produkti atbilst prasībām saskaņā ar Regulu (ES) 2017/745 par medicīniskajām ierīcēm, lietojot saskaņotos standartus EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021 un EN ISO 15223-1:2021. Šie produkti ir klasificēti kā I klases medicīniskās ierīces.

Už šią atitikties deklaraciją atsako tik „LM-Instruments Oy“. Šiuo dokumentu deklaruojame, kad A priede išvardyti gaminiai atitinka reglamentą (ES) 2017/745 dėl medicinos priemonių, vadovaujantis darniaisiais standartais EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021 ir EN ISO 15223-1:2021. Gaminiai klasifikuojami kaip I klasės medicinos priemonės.

DEKLARACJA ZGODNOŚCI (PL)
DECLARAÇÃO DE CONFORMIDADE (PT)
DECLARAȚIE DE CONFORMITATE (RO)
VYHLÁSENIE O ZHODE (SK)
IZJAVA O SKLADNOSTI (SL)

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ROZPORZĄDZENIE PARLAMENTU EUROPEJSKIEGO I RADY (UE) 2017/745 W SPRAWIE WYROBÓW MEDYCZNYCH

REGULAMENTO (UE) 2017/745 DO PARLAMENTO EUROPEU E DO CONSELHO SOBRE DISPOSITIVOS MÉDICOS

REGULAMENTUL (UE) 2017/745 AL PARLAMENTULUI EUROPEAN ȘI AL CONSILIULUI PRIVIND DISPOZITIVELE MEDICALE

NARIADENIE (EÚ) 2017/745 EURÓPSKEHO PARLAMENTU A RADY O ZDRAVOTNÍCKYCH ZARIADENIACH

UREDBA (EU) 2017/745 EVROPSKEGA PARLAMENTA IN SVETA O MEDICINSKIH PRIPOMOČKIH

Producent: LM-Instruments Oy
Fabricante: SRN: FI-MF-000006705
Producător: Norrbyn rantatie 8
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Wyłączną odpowiedzialność za niniejszą deklarację zgodności ponosi LM-Instruments Oy. Niniejszym deklarujemy, że produkty wymienione w załączniku A są zgodne z wymogami rozporządzenia (UE) 2017/745 dotyczącego urządzeń medycznych dzięki zastosowaniu zharmonizowanych norm EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021 oraz EN ISO 15223-1:2021. Produkty są sklasyfikowane jako wyroby medyczne klasy I.

A presente declaração de conformidade é da exclusiva responsabilidade da LM-Instruments Oy. Pela presente, declaramos que os produtos descritos no anexo A cumprem os regulamentos (UE) 2017/745 relativos a dispositivos médicos através da aplicação das normas harmonizadas EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021 e EN ISO 15223-1:2021. Os produtos estão classificados como Dispositivos Médicos, Classe I.

Prezenta declarație de conformitate este dată sub responsabilitatea exclusivă a LM-Instruments Oy. Declarăm prin prezenta că produsele enumerate în anexa A respectă Regulamentul (UE) 2017/745 privind dispozitivele medicale prin aplicarea standardelor armonizate EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021 și EN ISO 15223-1:2021. Produsele sunt clasificate ca dispozitive medicale Clasa I.

Za toto vyhlásenie o zhode nesie výhradnú zodpovednosť spoločnosť LM-Instruments Oy. Týmto vyhlasujeme, že produkty uvedené v prílohe A sú v súlade s nariadením (EÚ) 2017/745 o zdravotníckych pomôckach uplatnením harmonizovaných noriem EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021 a EN ISO 15223-1:2021. Produkty sú klasifikované ako zdravotnícke pomôcky triedy I

Za to izjavo o skladnosti je izključno odgovorno podjetje LM-Instruments Oy. S tem izjavljamo, da so izdelki, navedeni v dodatku A, skladni z uredbo (EU) 2017/745 za medicinske pripomočke z uporabo harmoniziranih standardov EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021 in EN ISO 15223 -1:2021. Izdelki so razvrščeni kot medicinski pripomočki razreda I.

DECLARACIÓN DE CONFORMIDAD (ES) FÖRSÄKRAN OM ÖVERENSSTÄMMELSE (SV)



REGLAMENTO DE DISPOSITIVOS MÉDICOS (EU) 2017/745 DEL PARLAMENTO EUROPEO Y CONSEJO EUROPEO
EUROPAPARLAMENTETS OCH RÅDETS FÖRORDNING (EU) 2017/745 OM MEDICINTEKNISKA PRODUKTER

Fabricante: LM-Instruments Oy
Tillverkare: SRN: FI-MF-000006705
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Esta declaración de conformidad se realiza bajo la responsabilidad exclusiva de LM-Instruments Oy. Por la presente declaramos que los productos enumerados en el apéndice A cumplen con las regulaciones (UE) 2017/745 sobre dispositivos médicos mediante la aplicación de los estándares armonizados EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021 y EN ISO 15223-1:2021. Los productos están clasificados como dispositivos médicos de clase I.

Denna försäkrans om överensstämmelse är helt under LM-Instruments Oys ansvar. Härmed deklarerar vi att produkter som listas i bilaga A överensstämmer med förordningarna (EU) 2017/745 för medicintekniska produkter genom tillämpning av harmoniserade standarder EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021 och EN ISO 15223-1:2021. Produkterna klassificeras som medicintekniska produkter, klass I.

Parainen 19.9.2024

Timo Helenius

Managing Director
LM-Instruments Oy

Appendix A, Non-cutting restorative instruments

19.9.2024 rev. 10

MDR Class I based on rule 5

Intended use: Dental hand instrument for restorative operations

Basic UDI 6438311RESTO102Y

Code / Catalogue number	Trade Name
29H-30HES	Base Carrier, rigid
29H-30HEST	Base Carrier, rigid DTS
29H-30HESTU	Base Carrier, rigid DTS U
29H-30HSI	Base Carrier, rigid
29H-30HXS	Base Carrier, rigid
30-34ES	Base carrier Cond.malleab.tip
30-34EST	Base carrier Cond.malleab.tip DTS
30-34ESTU	Base carrier Cond.malleab.tip DTS U
30-34SI	Base carrier Cond.malleab.tip
30-34XS	Base carrier Cond.malleab.tip
307-308DES	Arte Eccesso DD
307-308DEST	Arte Eccesso DD DTS
307-308DESTU	Arte Eccesso DD DTS U
307-308ES	Arte Eccesso
307-308EST	Arte Eccesso DTS
307-308ESTU	Arte Eccesso DTS U
307-308XS	Arte Eccesso
30H-34ES	Base carrier-Condenser,rigid
30H-34EST	Base carrier-Condenser,rigid DTS
30H-34ESTU	Base carrier-Condenser,rigid DTS U
30H-34SI	Base carrier-Condenser,rigid
30H-34XS	Base carrier-Condenser,rigid
31-32DES	Burnisher
31-32DEST	Burnisher DTS
31-32DESTU	Burnisher DTS U
31-32ES	Burnisher
31-32EST	Burnisher DTS
31-32ESTU	Burnisher DTS U
31-32SI	Burnisher
31-32XS	Burnisher
340-360ES	Plugger cylindrical 1.0-1.5mm
340-360EST	Plugger cylindrical 1.0-1.5mm DTS
340-360ESTU	Plugger cylindrical 1.0-1.5mm DTS U
340-360SI	Plugger cylindrical 1.0-1.5mm
340-360XS	Plugger cylindrical 1.0-1.5mm
350-380ES	Plugger cylindrical 1.2-2.0mm
350-380EST	Plugger cylindrical 1.2-2.0mm DTS
350-380ESTU	Plugger cylindrical 1.2-2.0mm DTS U
350-380PDL	Plugger, cylindrical 1.2-2.0mm Orbis
350-380PDLM	Plugger, cylindrical 1.2-2.0mm Orbis
350-380SI	Plugger cylindrical 1.2-2.0mm
350-380XS	Plugger cylindrical 1.2-2.0mm
370-390ES	Plugger cylindrical 1.8-2.5mm

370-390EST	Plugger cylindrical 1.8-2.5mm DTS
370-390ESTU	Plugger cylindrical 1.8-2.5mm DTS U
370-390SI	Plugger cylindrical 1.8-2.5mm
370-390XSI	Plugger cylindrical 1.8-2.5mm
431-433ES	Arte Solo Anterior
431-433EST	Arte Solo Anterior DTS
431-433XSI	Arte Solo Anterior
434-438ES	Arte Solo Posterior
434-438EST	Arte Solo Posterior DTS
434-438XSI	Arte Solo Posterior
43-47DDES	Plastic instrument, anterior
43-47DDEST	Plastic instrument, anterior DTS
43-47DDESTU	Plastic instrument, anterior DTS U
43-47ES	Plastic instrument, anterior
43-47EST	Plastic instrument, anterior DTS
43-47ESTU	Plastic instrument, anterior DTS U
43-47PDLM	Plastic Instrument, anterior Orbis
43-47PDOLM	Plastic Instrument, anterior Orbis
43-47SI	Plastic instrument, anterior
43-47XSI	Plastic instrument, anterior
43-48XSI	Plastic instrument, anterior - posterior
442-443DDES	Arte Modella DD
442-443DDEST	Arte Modella DD DTS
442-443DDESTU	Arte Modella DD DTS U
442-443ES	Arte Modella
442-443EST	Arte Modella DTS
442-443ESTU	Arte Modella DTS U
442-443XSI	Arte Modella
444-445DDES	Mini Spatula
444-445DDEST	Mini Spatula DTS
444-445DDESTU	Mini Spatula DTS U
444-445ES	Mini Spatula
444-445EST	Mini Spatula DTS
444-445ESTU	Mini Spatula DTS U
444-445PDOLM	Mini Spatula Orbis
444-445SI	Mini Spatula
444-445XSI	Mini Spatula
445-360XSI	Mini Spatula - Plugger, cylindrical, 1.5mm
445-473XSI	Mini Spatula - Plugger, ball-ended, 2.5 mm
445-483XSI	Mini Spatula - Packer Modeller IO
445-702XSI	Mini Spatula - Packer-Modeller IO p
446-447ES	Composite Spatula 6
446-447EST	Composite Spatula 6 DTS
446-447ESTU	Composite Spatula 6 DTS U
446-447PDLM	Composite Spatula 6 Orbis
446-447SI	Composite Spatula 6
446-447XSI	Composite Spatula 6
448-449ES	Arte Replica Posterior
448-449EST	Arte Replica Posterior DTS
448-449ESTU	Arte Replica Posterior DTS U

448-449XSI	Arte Replica Posterior
450-460ES	Spatula
450-460EST	Spatula DTS
450-460ESTU	Spatula DTS U
450-460SI	Spatula
450-460XSI	Spatula
455-456XSI	StickSTEPPER
457-458XSI	StickCARRIER
464-494ES	Arte Applicia Twist
464-494EST	Arte Applicia Twist DTS
464-494ESTU	Arte Applicia Twist DTS U
464-494XSI	Arte Applicia Twist
46-49DDES	Arte Applicia DD
46-49DDEST	Arte Applicia DD DTS
46-49DDESTU	Arte Applicia DD DTS U
46-49ES	Arte Applicia
46-49EST	Arte Applicia DTS
46-49ESTU	Arte Applicia DTS U
46-49XSI	Arte Applicia
468-469ES	Arte Cusp Misura
468-469EST	Arte Cusp Misura DTS
468-469XSI	Arte Cusp Misura
471-472XSI	Burnisher - Plugger, ball-ended, 1.5-2.0 mm
471-473DDES	Burnisher-Plugger 1.5-2.5mm ball-ended
471-473DDEST	Burnisher-Plugger 1.5-2.5mm ball-ended DTS
471-473DDESTU	Burnisher-Plugger 1.5-2.5mm ball-ended DTS U
471-473ES	Burnisher-Plugger 1.5-2.5mm ball-ended
471-473EST	Burnisher-Plugger 1.5-2.5mm ball-ended DTS
471-473ESTU	Burnisher-Plugger 1.5-2.5mm ball-ended DTS U
471-473PDLM	Burnisher-plugger, ball-ended 1.5-2.5mm Orbis
471-473PDOLM	Burnisher-plugger, ball-ended 1.5-2.5mm Orbis
471-473SI	Burnisher-Plugger 1.5-2.5mm ball-ended
471-473XSI	Burnisher-Plugger 1.5-2.5mm, ball-ended
476-477ES	Burnisher 27-29
476-477EST	Burnisher 27-29 DTS
476-477ESTU	Burnisher 27-29 DTS U
476-477SI	Burnisher 27-29
476-477XSI	Burnisher 27-29
481-487DDES	Arte Fissura DD
481-487DDEST	Arte Fissura DD DTS
481-487DDESTU	Arte Fissura DD DTS U
481-487ES	Arte Fissura
481-487EST	Arte Fissura DTS
481-487ESTU	Arte Fissura DTS U
481-487XSI	Arte Fissura
482-483DDES	Packer-Modeller IO
482-483DDEST	Packer-Modeller IO DTS
482-483DDESTU	Packer-Modeller IO DTS U
482-483ES	Packer-Modeller IO
482-483EST	Packer-Modeller IO DTS

482-483ESTU	Packer-Modeller IO DTS U
482-483SI	Packer-Modeller IO
482-483XSI	Packer-Modeller IO
482-702ES	Packer-Modeller IO
482-702EST	Packer-Modeller IO DTS
482-702ESTU	Packer-Modeller IO DTS U
482-702SI	Packer-Modeller IO
482-702XSI	Packer-Modeller IO
483-703ES	Packer-Modeller IO
483-703EST	Packer-Modeller IO DTS
483-703ESTU	Packer-Modeller IO DTS U
483-703SI	Packer-Modeller IO
483-703XSI	Packer-Modeller IO
484-485ES	Flow Instrument IO
484-485EST	Flow Instrument IO DTS
484-485ESTU	Flow Instrument IO DTS U
484-485XSI	Flow Instrument IO
48-702DDES	Plastic Instrument,posterior
48-702DDEST	Plastic Instrument,posterior DTS
48-702DDESTU	Plastic Instrument,posterior DTS U
48-702ES	Plastic instrument, posterior
48-702EST	Plastic instrument, posterior DTS
48-702ESTU	Plastic instrument, posterior DTS U
48-702PDLM	Plastic Instrument, posterior Orbis
48-702PDOLM	Plastic Instrument, posterior Orbis
48-702SI	Plastic instrument, posterior
48-702XSI	Plastic instrument, posterior
488-489DDES	Arte Condensa DD
488-489DDEST	Arte Condensa DD DTS
488-489DDESTU	Arte Condensa DD DTS U
488-489ES	Arte Condensa
488-489EST	Arte Condensa DTS
488-489ESTU	Arte Condensa DTS U
488-489XSI	Arte Condensa
490-491ES	Cord Packer 2.0mm
490-491EST	Cord Packer 2.0mm DTS
490-491ESTU	Cord Packer 2.0mm DTS U
490-491SI	Cord Packer 2.0mm
490-491XSI	Cord Packer 2.0mm
492-493ES	Cord Packer 2.6mm
492-493EST	Cord Packer 2.6mm DTS
492-493ESTU	Cord Packer 2.6mm DTS U
492-493SI	Cord Packer 2.6mm
492-493XSI	Cord Packer 2.6mm
496-497ES	Arte Misura
496-497EST	Arte Misura DTS
496-497ESTU	Arte Misura DTS U
496-497XSI	Arte Misura
498-499ES	Arte Posterior Misura
498-499EST	Arte Posterior Misura DTS

498-499ESTU	Arte Posterior Misura DTS U
498-499XSI	Arte Posterior Misura
6657ES	LM-CompoSet
6657XSI	LM-CompoSet
6840ES	ArteSet
6840XSI	ArteSet
6844ES	Arte Posterior Set
6844XSI	Arte Posterior Set
6845ES	LM-Arte Dark Diamond Set
6848ES	Arte Complete Set
6848XSI	Arte Complete Set
702-703ES	Form Condenser 1.5-2.5mm
702-703EST	Form Condenser 1.5-2.5mm DTS
702-703ESTU	Form Condenser 1.5-2.5mm DTS U
702-703PDOLM	Form Condenser 1.5-2.5mm Orbis
702-703SI	Form Condenser 1.5-2.5mm
702-703XSI	Form Condenser 1.5-2.5mm
707-708DDES	Modeller MH Mini
707-708DDEST	Modeller MH Mini DTS
707-708DDESTU	Modeller MH Mini DTS U
707-708ES	Modeller MH Mini
707-708EST	Modeller MH Mini DTS
707-708ESTU	Modeller MH Mini DTS U
707-708XSI	Modeller MH Mini
708-709DDES	Modeller MH
708-709DDEST	Modeller MH DTS
708-709DDESTU	Modeller MH DTS U
708-709ES	Modeller MH
708-709EST	Modeller MH DTS
708-709ESTU	Modeller MH DTS U
708-709XSI	Modeller MH
71-72ES	Universal Carver occlusal-proximal
71-72EST	Universal Carver occlusal-proximal DTS
71-72ESTU	Universal Carver occlusal-proximal DTS U
71-72SI	Universal Carver occlusal-proximal
71-72XSI	Universal Carver occlusal-proximal
71-73ES	Maehlum
71-73EST	Maehlum DTS
71-73ESTU	Maehlum DTS U
71-73SI	Maehlum
71-73XSI	Maehlum
731-732ES	Cleoid-Discoïd
731-732EST	Cleoid-Discoïd DTS
731-732ESTU	Cleoid-Discoïd DTS U
731-732SI	Cleoid-Discoïd
731-732XSI	Cleoid-Discoïd
741-751ES	Hollenback 1/2
741-751EST	Hollenback 1/2 DTS
741-751ESTU	Hollenback 1/2 DTS U
741-751SI	Hollenback 1/2

741-751XSI	Hollenback 1/2
74-481XSI	Nyström I - Modeller
74-75ES	Nyström I
74-75EST	Nyström I DTS
74-75ESTU	Nyström I DTS U
74-75PDOLM	Carver Nyström I Orbis
74-75SI	Nyström I
74-75XSI	Nyström I
7500	Gingival Retractors Assortment
7502	Gingival Retractors S
7504	Gingival Retractors M
7506	Gingival Retractors XL
750-756ES	Multiholder PK I
750-756EST	Multiholder PK I DTS
750-756ESTU	Multiholder PK I DTS U
750-756SI	Multiholder PK I
750-756XSI	Multiholder PK I
752-754ES	Multiholder PK II
752-754EST	Multiholder PK II DTS
752-754ESTU	Multiholder PK II DTS U
752-754SI	Multiholder PK II
752-754XSI	Multiholder PK II
752-756ES	Multiholder PK III Gengiva
752-756EST	Multiholder PK III Gengiva DTS
752-756ESTU	Multiholder PK III Gengiva DTS U
752-756XSI	Multiholder PK III Gengiva
7555	Intro assortment, working ends
7555KES	LM-MultiHolder IntroKit
7555KXSI	LM-MultiHolder IntroKit
7556KES	LM-GengivaKit
7556KXSI	LM-GengivaKit
7600	Cervical Matrices Assortment
7602	Cervical Matrices for incisors
7604	Cervical Matrices for canines and premolars
7606	Cervical Matrices for small molars
7608	Cervical Matrices for large molars
7620	Contact Formers Assortment
7622	Contact Formers XS
7624	Contact Formers S
7626	Contact Formers M
7628	Contact Formers L
764-766ES	Filling Remover
764-766EST	Filling Remover DTS
764-766ESTU	Filling Remover DTS U
764-766SI	Filling Remover
764-766XSI	Filling Remover
767-768ES	Crown Off
767-768EST	Crown Off DTS
767-768ESTU	Crown Off DTS U
767-768XSI	Crown Off

76-77ES	Nyström III
76-77EST	Nyström III DTS
76-77ESTU	Nyström III DTS U
76-77PDLM	Carver Nyström III Orbis
76-77PDOLM	Carver Nyström III Orbis
76-77SI	Nyström III
76-77XSI	Nyström III
784-794ES	Excess Scaler Mini
784-794EST	Excess Scaler Mini DTS
784-794ESTU	Excess Scaler Mini DTS U
784-794SI	Excess Scaler Mini
784-794XSI	Excess Scaler Mini
785-795ES	Excess Scaler
785-795EST	Excess Scaler DTS
785-795ESTU	Excess Scaler DTS U
785-795SI	Excess Scaler
785-795XSI	Excess Scaler
S444-445ESTGREY	Mini Spatula DTS
S482-483ESTGREY	Packer-Modeller IO DTS
S48-702ESTGREY	Plastic instrument, posterior DTS
S48-702ESTORANGE	Plastic instrument, posterior DTS
S490-491ESTRED	Cord packer 2,0mm DTS

Appendix A, diagnostic instruments

MDR Class I based on rule 5

Intended use: Dental hand instrument for diagnostic operations

Basic UDI 6438311DIAGNO10QV

Code / Catalogue number	Trade name
11-12ES	Explorer
11-12EST	Explorer DTS
11-12ESTU	Explorer DTS U
11-12SI	Explorer
11-12XSI	Explorer
11F-12FES	Flexplorer
11F-12FEST	Flexplorer DTS
11F-12FESTU	Flexplorer DTS U
11F-12FXSI	Flexplorer
17-23ES	Explorer
17-23EST	Explorer DTS
17-23ESTU	Explorer DTS U
17-23SI	Explorer
17-23XSI	Explorer
17C-23ES	Explorer, centered
17C-23EST	Explorer, centered DTS
17C-23SI	Explorer, centered
17C-23XSI	Explorer, centered
17CXSI	Explorer, centered, se
17ES	Explorer, se
17EST	Explorer, se DTS
18-19ES	Explorer, prosthetic
18-19EST	Explorer, prosthetic DTS
18-19ESTU	Explorer, prosthetic DTS U
18-19SI	Explorer, prosthetic
18-19XSI	Explorer, prosthetic
20-21ES	Nabers Probe
20-21EST	Nabers Probe DTS
20-21ESTU	Nabers Probe DTS U
20-21SI	Nabers Probe
20-21XSI	Nabers Probe
20B-21BES	Furcation Probe
20B-21BEST	Furcation Probe DTS
20B-21BESTU	Furcation Probe DTS U
20B-21BSI	Furcation Probe
20B-21BXSI	Furcation Probe
23-520BES	Explorer-Periodontal probe
23-520BEST	Explorer-Periodontal probe DTS
23-520BESTU	Explorer-Periodontal probe DTS U
23-520BSI	Explorer-Periodontal probe
23-520BXSI	Explorer-Periodontal probe
23-52BES	Explorer-Periodontal probe
23-52BEST	Explorer-Periodontal probe DTS

23-52BESTU	Explorer-Periodontal probe DTS U
23-52BSI	Explorer-Periodontal probe
23-52BXSI	Explorer-Periodontal probe
23-530BES	Explorer-Periodontal probe
23-530BEST	Explorer-Periodontal probe DTS
23-530BESTU	Explorer-Periodontal probe DTS U
23-530BSI	Explorer-Periodontal probe
23-530BXSI	Explorer-Periodontal probe
23-54BESTU	Explorer-North Carolina Probe, DTS U
23-550BES	Explorer-WHO Probe
23-550BEST	Explorer-WHO Probe DTS
23-550BSI	Explorer-WHO Probe
23-550BXSI	Explorer-WHO Probe
23ES	Explorer, se
23EST	Explorer, se DTS
23SI	Explorer, se
23XSI	Explorer, se
25-473ES	Mirror handle JM
25-473EST	Mirror handle JM DTS
25-473ESTU	Mirror handle JM DTS U
25-473XSI	Mirror handle JM
25-26ES	Mirror handle, ortho
25-26EST	Mirror handle, ortho DTS
25-26ESTU	Mirror handle, ortho DTS U
25-26XSI	Mirror handle, ortho
25ESBLUE	Mirror handle 25 ES blue
25ESBLUET	Mirror handle 25 ES blue DTS
25ESGREY	Mirror handle 25 ES grey
25ESGREYT	Mirror handle 25 ES grey DTS
25ESGREYTU	Mirror handle 25 ES grey DTS U
25ESIBLUE	Mirror handle 25 Esi blue
25ESIGREY	Mirror handle 25 Esi grey
25ESIRED	Mirror handle 25 Esi red
25ESRED	Mirror handle 25 ES red
25ESREDT	Mirror handle 25 ES red DTS
25SIBLUE	Mirror handle 25 si blue
25SIGREY	Mirror handle 25 si grey
25SIRED	Mirror handle 25 si red
25XSIBLUE	Mirror handle 25 Xsi blue
25XSIGREY	Mirror handle 25 Xsi grey
25XSIRED	Mirror handle 25 Xsi red
28-26ES	Mirror handle UNF4-48, Ortho
28-26EST	Mirror handle UNF4-48, Ortho DTS
28-26ESTU	Mirror handle UNF4-48, Ortho DTS U
28-26XSI	Mirror handle UNF4-48, Ortho
28ESBLUE	Mirror handle 28 ES blue UNF4-48
28ESBLUET	Mirror handle 28 ES blue UNF4-48 DTS
28ESGREY	Mirror handle 28 ES grey UNF4-48
28ESGREYT	Mirror handle 28 ES grey UNF4-48 DTS
28ESIBLUE	Mirror handle 28 Esi blue UNF4-48

28ESIGREY	Mirror handle 28 Esi grey UNF4-48
28ESIRED	Mirror handle 28 Esi red UNF4-48
28ESRED	Mirror handle 28 ES red UNF4-48
28ESREDT	Mirror handle 28 ES red UNF4-48 DTS
28XSIBLUE	Mirror handle 28 Xsi blue UNF4-48
28XSIGREY	Mirror handle 28 Xsi grey UNF4-48
28XSIRED	Mirror handle 28 Xsi red UNF4-48
29ES	Explorer, Holst, se
29EST	Explorer, Holst, se DTS
29ESTU	Explorer, Holst, se DTS U
29SI	Explorer, Holst, se
29XSI	Explorer, Holst, se
3-6ES	Explorer
3-6EST	Explorer DTS
3-6ESTU	Explorer DTS U
3-6XSI	Explorer
51ES	Williams Probe, se
51EST	Williams Probe, se DTS
51SI	Williams Probe, se
51XSI	Williams Probe, se
520BES	Periodontal probe, se
520BEST	Periodontal probe, se DTS
520BESTU	Periodontal probe, se DTS U
520BSI	Periodontal probe, se
520BXSI	Periodontal probe, se
52BES	Periodontal probe, se
52BEST	Periodontal probe, se DTS
52BESTU	Periodontal probe, se DTS U
52BSI	Periodontal probe, se
52BXSI	Periodontal probe, se
530BES	Periodontal probe, se
530BEST	Periodontal probe, se DTS
530BESTU	Periodontal probe, se DTS U
530BSI	Periodontal probe, se
530BXSI	Periodontal probe, se
53BES	Marquis 12 Probe, se
53BEST	Marquis 12 Probe, se DTS
53BXSI	Marquis 12 Probe, se
54BES	North Carolina Probe, se
54BEST	North Carolina Probe, se DTS
54BXSI	North Carolina Probe, se
550BES	WHO Probe, se
550BEST	WHO Probe, se DTS
550BESTU	WHO Probe, se DTS U
550BSI	WHO Probe, se
550BXSI	WHO Probe, se
5-8ES	Explorer
5-8EST	Explorer DTS
5-8ESTU	Explorer DTS U
5-8SI	Explorer

5-8XSI	Explorer
5-9ES	Explorer
5-9EST	Explorer DTS
5-9ESTU	Explorer DTS U
5-9SI	Explorer
5-9XSI	Explorer
6ES	Explorer, se
8ES	Explorer, se
8-520BES	Explorer-Periodontal Probe
8-520BEST	Explorer-Periodontal Probe DTS
8-520BESTU	Explorer-Periodontal Probe DTS U
8-520BSI	Explorer-Periodontal Probe
8-520BXSI	Explorer-Periodontal Probe
8-550BES	Explorer-WHO Probe
8-550BEST	Explorer-WHO Probe DTS
8-550BSI	Explorer-WHO Probe
8-550BXSI	Explorer-WHO Probe
9-17CES	Explorer, centered
9-17CEST	Explorer, centered DTS
9-17CESTU	Explorer, centered DTS U
9-17CXSI	Explorer, centered
9ES	Explorer, se
9EST	Explorer, se DTS
9SI	Explorer, se
9XSI	Explorer, se
S25ESTYELLOW	Mirror handle, yellow DTS
S25ESTORANGE	Mirror handle, orange DTS
S25ESTGREEN	Mirror handle, green DTS
S17C-23ESTYELLOW	Explorer DTS
S17C-23ESTBLUE	Explorer DTS
S17C-23ESTGREEN	Explorer DTS
S17C-23ESTRED	Explorer DTS
S51ESTBLUE	Williams probe DTS
S51ESTYELLOW	Williams probe DTS
S51ESTGREY	Williams probe DTS
S51ESTGREEN	Williams probe DTS
S51ESTRED	Williams probe DTS
9-23XSI	Explorer 9-23
25PDOLM	Mirror handle 25 (blue) Orbis
5-8PDOLM	Explorer Orbis
29PDOLM	Explorer, Holst, se Orbis
18-19PDOLM	Explorer, prosthetic Orbis
23-520BPDOLM	Explorer-Periodontal probe Orbis
550BPDOLM	WHO Probe, se Orbis
5-9PDLM	Explorer Orbis
17-23PDLM	Explorer Orbis
17C-23ESTU	Explorer, centered DTS U
17CSI	Explorer, centered, se
17ESTU	Explorer, se DTS U
17XSI	Explorer, se

23-51ES	Explorer-Williams Probe
23-51EST	Explorer-Williams Probe DTS
23-51XSI	Explorer-Williams Probe
23-54BES	Explorer - North Carolina Probe 54B
23-550BESTU	Explorer-WHO Probe DTS U
23ESTU	Explorer, se DTS U
25ESBLUETU	Mirror handle 25 ES blue DTS U
25ESREDTU	Mirror handle 25 ES red DTS U
25PDLM	Mirror handle 25 Orbis
28ESBLUETU	Mirror handle 28 ES blue UNF4-48 DTS U
28ESGREYTU	Mirror handle 28 ES grey UNF4-48 DTS U
28ESREDTU	Mirror handle 28 ES red UNF4-48 DTS U
3-6SI	Explorer
51ESTU	Williams Probe, se DTS U
53BESTU	Marquis 12 Probe, se DTS U
54BESTU	North Carolina Probe, se DTS U
5SI	Explorer, se
5XSI	Explorer, se
6XSI	Explorer, se
8-550BESTU	Explorer-WHO Probe DTS U
8EST	Explorer, se DTS
8ESTU	Explorer, se DTS U
8XSI	Explorer, se
9-17CSI	Explorer, centered
99911F12FES	Flexplorer ErgoSense (With Compliments)
99911F12FXSI	Flexplorer ErgoMax (With Compliments)
9ESTU	Explorer, se DTS U

Appendix A, endodontic instruments

MDR Class I based on rule 5

Intended use: Dental hand instrument for endodontic operations

Basic UDI 6438311ENDO10PV

Code / Catalogue number	Trade Name
41-42ES	Endo Plugger 0.5-1.0mm
41-42EST	Endo Plugger 0.5-1.0mm DTS
41-42SI	Endo Plugger 0.5-1.0mm
41-42XSI	Endo Plugger 0.5-1.0mm
22-24ESTU	Endo Spreader DTS U DE special 0,23 / 0,4mm
22ES	Endo Spreader 0,23mm
22EST	Endo Spreader 0,23mm DTS
22XSI	Endo Spreader 0,23mm
24ES	Endo Spreader 0,4mm
24EST	Endo Spreader 0,4mm DTS
24ESTU	Endo Spreader 0,4mm DTS U
24XSI	Endo Spreader 0,4mm
S41-42ESTORANGE	Endo plugger 0,5-1,0 mm DTS
41-42ESTU	Endo Plugger 0.5-1.0mm DTS U
22ESTU	Endo Spreader 0,23mm DTS U
27-28ES	Root Canal Explorer
27-28SI	Root Canal Explorer
27-28XSI	Root Canal Explorer
27-28EST	Root Canal Explorer DTS
S27-28ESTORANGE	Root canal explorer DTS
27-28ESTU	Root Canal Explorer DTS U

Appendix A, orthodontic instruments

MDR Class I based on rule 5

Intended use: Dental hand instrument for orthodontic operations

Basic UDI 6438311ORTHO104D

Code / Catalogue number	Trade Name
411-415ES	Ligature Director
411-415EST	Ligature Director DTS
411-415ESTU	Ligature Director DTS U
411-415XSI	Ligature Director
412-413ES	Arch Wire Tucker
412-413EST	Arch Wire Tucker DTS
412-413ESTU	Arch Wire Tucker DTS U
412-413XSI	Arch Wire Tucker
414-150ES	Ligature Tucker-Scaler U15
414-150EST	Ligature Tucker-Scaler U15 DTS
414-150SI	Ligature Tucker-Scaler U15
414-150XSI	Ligature Tucker-Scaler U15
414-17CLES	Ligature On Off SL
414-17CLEST	Ligature On Off SL DTS
414-17CLESTU	Ligature On Off SL DTS U
414-17CLXSI	Ligature On Off SL
414-415ES	Ligature Tucker
414-415EST	Ligature Tucker DTS
414-415ESTU	Ligature Tucker DTS U
414-415SI	Ligature Tucker
414-415XSI	Ligature Tucker
416-417ES	Plastic Ligature Applicator
416-417EST	Plastic Ligature Applicator DTS
416-417ESTU	Plastic Ligature Applicator DTS U
416-417SI	Plastic Ligature Applicator
416-417XSI	Plastic Ligature Applicator
414-150ESTU	Ligature Tucker-Scaler U15 DTS U
423XSI	RMO Ligature Remover
436-437XSI	RMO Liberty Bielle Instrument

Appendix A, removable orthodontic appliances

MDR Class I based on rule 5

Intended use: Removable orthodontic appliance

Basic UDI 6438311ROA10UU

Code / Catalogue number	Trade name
94020HS	LM-Activator 20HIGH (short)
94020LS	LM-Activator 20LOW (short)
94025HS	LM-Activator 25HIGH (short)
94025LS	LM-Activator 25LOW (short)
94030HS	LM-Activator 30HIGH (short)
94030LS	LM-Activator 30LOW (short)
94035HS	LM-Activator 35HIGH (short)
94035LS	LM-Activator 35LOW (short)
94040HS	LM-Activator 40HIGH (short)
94040L	LM-Activator 40LOW
94040LS	LM-Activator 40LOW (short)
94045H	LM-Activator 45HIGH
94045HS	LM-Activator 45HIGH (short)
94045L	LM-Activator 45LOW
94045LR	LM-Activator 45LOW Reinforced
94045LS	LM-Activator 45LOW (short)
94050H	LM-Activator 50HIGH
94050HS	LM-Activator 50HIGH (short)
94050L	LM-Activator 50LOW
94050LR	LM-Activator 50LOW Reinforced
94050LS	LM-Activator 50LOW (short)
94055H	LM-Activator 55HIGH
94055HS	LM-Activator 55HIGH (short)
94055L	LM-Activator 55LOW
94055LR	LM-Activator 55LOW Reinforced
94055LS	LM-Activator 55LOW (short)
94060H	LM-Activator 60HIGH
94060HS	LM-Activator 60HIGH (short)
94060L	LM-Activator 60LOW
94060LR	LM-Activator 60LOW Reinforced
94060LS	LM-Activator 60LOW (short)
94065H	LM-Activator 65HIGH
94065HS	LM-Activator 65HIGH (short)
94065L	LM-Activator 65LOW
94065LS	LM-Activator 65LOW (short)
94070H	LM-Activator 70HIGH
94070HS	LM-Activator 70HIGH (short)
94070L	LM-Activator 70LOW
94070LS	LM-Activator 70LOW (short)
94235HLN	LM-Activator2 High Long 35 Narrow
94235HLNR	LM-Activator2 High Long 35 Narrow Reinforced
94235HLW	LM-Activator2 High Long 35 Wide
94235HLWR	LM-Activator2 High Long 35 Wide Reinforced
94235HSN	LM-Activator2 High Short 35 Narrow

94235HSNR	LM-Activator2 High Short 35 Narrow Reinforced
94235HSW	LM-Activator2 High Short 35 Wide
94235HSWR	LM-Activator2 High Short 35 Wide Reinforced
94235LLN	LM-Activator2 Low Long 35 Narrow
94235LLNR	LM-Activator2 Low Long 35 Narrow Reinforced
94235LLW	LM-Activator2 Low Long 35 Wide
94235LLWR	LM-Activator2 Low Long 35 Wide Reinforced
94235LSN	LM-Activator2 Low Short 35 Narrow
94235LSNR	LM-Activator2 Low Short 35 Narrow Reinforced
94235LSW	LM-Activator2 Low Short 35 Wide
94235LSWR	LM-Activator2 Low Short 35 Wide Reinforced
94240HLN	LM-Activator2 High Long 40 Narrow
94240HLNR	LM-Activator2 High Long 40 Narrow Reinforced
94240HLW	LM-Activator2 High Long 40 Wide
94240HLWR	LM-Activator2 High Long 40 Wide Reinforced
94240HSN	LM-Activator2 High Short 40 Narrow
94240HSNR	LM-Activator2 High Short 40 Narrow Reinforced
94240HSW	LM-Activator2 High Short 40 Wide
94240HSWR	LM-Activator2 High Short 40 Wide Reinforced
94240LLN	LM-Activator2 Low Long 40 Narrow
94240LLNR	LM-Activator2 Low Long 40 Narrow Reinforced
94240LLW	LM-Activator2 Low Long 40 Wide
94240LLWR	LM-Activator2 Low Long 40 Wide Reinforced
94240LSN	LM-Activator2 Low Short 40 Narrow
94240LSNR	LM-Activator2 Low Short 40 Narrow Reinforced
94240LSW	LM-Activator2 Low Short 40 Wide
94240LSWR	LM-Activator2 Low Short 40 Wide Reinforced
94245HLN	LM-Activator2 High Long 45 Narrow
94245HLNR	LM-Activator2 High Long 45 Narrow Reinforced
94245HLW	LM-Activator2 High Long 45 Wide
94245HLWR	LM-Activator2 High Long 45 Wide Reinforced
94245HSN	LM-Activator2 High Short 45 Narrow
94245HSNR	LM-Activator2 High Short 45 Narrow Reinforced
94245HSW	LM-Activator2 High Short 45 Wide
94245HSWR	LM-Activator2 High Short 45 Wide Reinforced
94245LLN	LM-Activator2 Low Long 45 Narrow
94245LLNR	LM-Activator2 Low Long 45 Narrow Reinforced
94245LLW	LM-Activator2 Low Long 45 Wide
94245LLWR	LM-Activator2 Low Long 45 Wide Reinforced
94245LSN	LM-Activator2 Low Short 45 Narrow
94245LSNR	LM-Activator2 Low Short 45 Narrow Reinforced
94245LSW	LM-Activator2 Low Short 45 Wide
94245LSWR	LM-Activator2 Low Short 45 Wide Reinforced
94250HLN	LM-Activator2 High Long 50 Narrow
94250HLNR	LM-Activator2 High Long 50 Narrow Reinforced
94250HLW	LM-Activator2 High Long 50 Wide
94250HLWR	LM-Activator2 High Long 50 Wide Reinforced
94250HSN	LM-Activator2 High Short 50 Narrow
94250HSNR	LM-Activator2 High Short 50 Narrow Reinforced
94250HSW	LM-Activator2 High Short 50 Wide

94250HSWR	LM-Activator2 High Short 50 Wide Reinforced
94250LLN	LM-Activator2 Low Long 50 Narrow
94250LLNR	LM-Activator2 Low Long 50 Narrow Reinforced
94250LLW	LM-Activator2 Low Long 50 Wide
94250LLWR	LM-Activator2 Low Long 50 Wide Reinforced
94250LSN	LM-Activator2 Low Short 50 Narrow
94250LSNR	LM-Activator2 Low Short 50 Narrow Reinforced
94250LSW	LM-Activator2 Low Short 50 Wide
94250LSWR	LM-Activator2 Low Short 50 Wide Reinforced
94255HLN	LM-Activator2 High Long 55 Narrow
94255HLNR	LM-Activator2 High Long 55 Narrow Reinforced
94255HLW	LM-Activator2 High Long 55 Wide
94255HLWR	LM-Activator2 High Long 55 Wide Reinforced
94255HSN	LM-Activator2 High Short 55 Narrow
94255HSNR	LM-Activator2 High Short 55 Narrow Reinforced
94255HSW	LM-Activator2 High Short 55 Wide
94255HSWR	LM-Activator2 High Short 55 Wide Reinforced
94255LLN	LM-Activator2 Low Long 55 Narrow
94255LLNR	LM-Activator2 Low Long 55 Narrow Reinforced
94255LLW	LM-Activator2 Low Long 55 Wide
94255LLWR	LM-Activator2 Low Long 55 Wide Reinforced
94255LSN	LM-Activator2 Low Short 55 Narrow
94255LSNR	LM-Activator2 Low Short 55 Narrow Reinforced
94255LSW	LM-Activator2 Low Short 55 Wide
94255LSWR	LM-Activator2 Low Short 55 Wide Reinforced
94260HLN	LM-Activator2 High Long 60 Narrow
94260HLNR	LM-Activator2 High Long 60 Narrow Reinforced
94260HLW	LM-Activator2 High Long 60 Wide
94260HLWR	LM-Activator2 High Long 60 Wide Reinforced
94260HSN	LM-Activator2 High Short 60 Narrow
94260HSNR	LM-Activator2 High Short 60 Narrow Reinforced
94260HSW	LM-Activator2 High Short 60 Wide
94260HSWR	LM-Activator2 High Short 60 Wide Reinforced
94260LLN	LM-Activator2 Low Long 60 Narrow
94260LLNR	LM-Activator2 Low Long 60 Narrow Reinforced
94260LLW	LM-Activator2 Low Long 60 Wide
94260LLWR	LM-Activator2 Low Long 60 Wide Reinforced
94260LSN	LM-Activator2 Low Short 60 Narrow
94260LSNR	LM-Activator2 Low Short 60 Narrow Reinforced
94260LSW	LM-Activator2 Low Short 60 Wide
94260LSWR	LM-Activator2 Low Short 60 Wide Reinforced
94265HLN	LM-Activator2 High Long 65 Narrow
94265HLNR	LM-Activator2 High Long 65 Narrow Reinforced
94265HLW	LM-Activator2 High Long 65 Wide
94265HLWR	LM-Activator2 High Long 65 Wide Reinforced
94265HSN	LM-Activator2 High Short 65 Narrow
94265HSNR	LM-Activator2 High Short 65 Narrow Reinforced
94265HSW	LM-Activator2 High Short 65 Wide
94265HSWR	LM-Activator2 High Short 65 Wide Reinforced
94265LLN	LM-Activator2 Low Long 65 Narrow

94265LLNR	LM-Activator2 Low Long 65 Narrow Reinforced
94265LLW	LM-Activator2 Low Long 65 Wide
94265LLWR	LM-Activator2 Low Long 65 Wide Reinforced
94265LSN	LM-Activator2 Low Short 65 Narrow
94265LSNR	LM-Activator2 Low Short 65 Narrow Reinforced
94265LSW	LM-Activator2 Low Short 65 Wide
94265LSWR	LM-Activator2 Low Short 65 Wide Reinforced
94270HLN	LM-Activator2 High Long 70 Narrow
94270HLNR	LM-Activator2 High Long 70 Narrow Reinforced
94270HLW	LM-Activator2 High Long 70 Wide
94270HLWR	LM-Activator2 High Long 70 Wide Reinforced
94270HSN	LM-Activator2 High Short 70 Narrow
94270HSNR	LM-Activator2 High Short 70 Narrow Reinforced
94270HSW	LM-Activator2 High Short 70 Wide
94270HSWR	LM-Activator2 High Short 70 Wide Reinforced
94270LLN	LM-Activator2 Low Long 70 Narrow
94270LLNR	LM-Activator2 Low Long 70 Narrow Reinforced
94270LLW	LM-Activator2 Low Long 70 Wide
94270LLWR	LM-Activator2 Low Long 70 Wide Reinforced
94270LSN	LM-Activator2 Low Short 70 Narrow
94270LSNR	LM-Activator2 Low Short 70 Narrow Reinforced
94270LSW	LM-Activator2 Low Short 70 Wide
94270LSWR	LM-Activator2 Low Short 70 Wide Reinforced
943104113	LM-Dental 104113
943104243	LM-Dental 104243
943105313	LM-Dental 105313
943112345	LM-Dental 112345
943112346	LM-Dental 112346
943112347	LM-Dental 112347
943112348	LM-Dental 112348
943117383	LM-Dental 117383
943120450	LM-Dental 120450
943120454	LM-Dental 120454
943121253	LM-Dental 121253
943122768	LM-Dental 122768
943125773	LM-Dental 125773
943133414	LM-Dental 133414
943134329	LM-Dental 134329
943134963	LM-Dental 134963
943140348	LM-Dental 140348
943142839	LM-Dental 142839
943144341	LM-Dental 144341
943145713	LM-Dental 145713
943146723	LM-Dental 146723
943147509	LM-Dental 147509
943156348	LM-Dental 156348
943158733	LM-Dental 158733
943165414	LM-Dental 165414
943166725	LM-Dental 166725
943171255	LM-Dental 171255

943173261	LM-Dental 173261
943177330	LM-Dental 177330
943184236	LM-Dental 184236
943185746	LM-Dental 185746
943197336	LM-Dental 197336
943197416	LM-Dental 197416
943197490	LM-Dental 197490
943201041	LM-Dental 201041
943205104	LM-Dental 205104
943209329	LM-Dental 209329
943210047	LM-Dental 210047
943223656	LM-Dental 223656
943241060	LM-Dental 241060
943245831	LM-Dental 245831
943248472	LM-Dental 248472
943249711	LM-Dental 249711
943252078	LM-Dental 252078
943254036	LM-Dental 254036
943254567	LM-Dental 254567
943255803	LM-Dental 255803
943261449	LM-Dental 261449
943264262	LM-Dental 264262
943269167	LM-Dental 269167
943269439	LM-Dental 269439
943276706	LM-Dental 276706
943281586	LM-Dental 281586
943285365	LM-Dental 285365
943290336	LM-Dental 290336
943297148	LM-Dental 297148
943304959	LM-Dental 304959
943306497	LM-Dental 306497
943317768	LM-Dental 317768
943325831	LM-Dental 325831
943327325	LM-Dental 327325
943330300	LM-Dental 330300
943333269	LM-Dental 333269
943336918	LM-Dental 336918
943343469	LM-Dental 343469
943344442	LM-Dental 344442
943350558	LM-Dental 350558
943354496	LM-Dental 354496
943357691	LM-Dental 357691
943358549	LM-Dental 358549
943372865	LM-Dental 372865
943377117	LM-Dental 377117
943381904	LM-Dental 381904
943398074	LM-Dental 398074
943398864	LM-Dental 398864
943406612	LM-Dental 406612
943411346	LM-Dental 411346

943415036	LM-Dental 415036
943415929	LM-Dental 415929
943425589	LM-Dental 425589
943434342	LM-Dental 434342
943435342	LM-Dental 435342
943435545	LM-Dental 435545
943435741	LM-Dental 435741
943440683	LM-Dental 440683
943443286	LM-Dental 443286
943450118	LM-Dental 450118
943452283	LM-Dental 452283
943452916	LM-Dental 452916
943461961	LM-Dental 461961
943464507	LM-Dental 464507
943466663	LM-Dental 466663
943471683	LM-Dental 471683
943477744	LM-Dental 477744
943479694	LM-Dental 479694
943485177	LM-Dental 485177
943498497	LM-Dental 498497
943503841	LM-Dental 503841
943505379	LM-Dental 505379
943507303	LM-Dental 507303
943511384	LM-Dental 511384
943511622	LM-Dental 511622
943522078	LM-Dental 522078
943522636	LM-Dental 522636
943526874	LM-Dental 526874
943529121	LM-Dental 529121
943530151	LM-Dental 530151
943542986	LM-Dental 542986
943545011	LM-Dental 545011
943546227	LM-Dental 546227
943551713	LM-Dental 551713
943560371	LM-Dental 560371
943560904	LM-Dental 560904
943563088	LM-Dental 563088
943563487	LM-Dental 563487
943565795	LM-Dental 565795
943570222	LM-Dental 570222
943574822	LM-Dental 574822
943585628	LM-Dental 585628
943591409	LM-Dental 591409
943594271	LM-Dental 594271
943602823	LM-Dental 602823
943609645	LM-Dental 609645
943615192	LM-Dental 615192
943625532	LM-Dental 625532
943625811	LM-Dental 625811
943627206	LM-Dental 627206

943632528	LM-Dental 632528
943633394	LM-Dental 633394
943642876	LM-Dental 642876
943644059	LM-Dental 644059
943645005	LM-Dental 645005
943647856	LM-Dental 647856
943656119	LM-Dental 656119
943658460	LM-Dental 658460
943659413	LM-Dental 659413
943661396	LM-Dental 661396
943663458	LM-Dental 663458
943672755	LM-Dental 672755
943702711	LM-Dental 702711
943722167	LM-Dental 722167
943723231	LM-Dental 723231
943728213	LM-Dental 728213
943728826	LM-Dental 728826
943736844	LM-Dental 736844
943739161	LM-Dental 739161
943740783	LM-Dental 740783
943750690	LM-Dental 750690
943765211	LM-Dental 765211
943765906	LM-Dental 765906
943768107	LM-Dental 768107
943777071	LM-Dental 777071
943782249	LM-Dental 782249
943783605	LM-Dental 783605
943792149	LM-Dental 792149
943799790	LM-Dental 799790
943806063	LM-Dental 806063
943809387	LM-Dental 809387
943810357	LM-Dental 810357
943811026	LM-Dental 811026
943811199	LM-Dental 811199
943823841	LM-Dental 823841
943824425	LM-Dental 824425
943831397	LM-Dental 831397
943833005	LM-Dental 833005
943837794	LM-Dental 837794
943839875	LM-Dental 839875
943844924	LM-Dental 844924
943845863	LM-Dental 845863
943846682	LM-Dental 846682
943854111	LM-Dental 854111
943860660	LM-Dental 860660
943868604	LM-Dental 868604
943870276	LM-Dental 870276
943882948	LM-Dental 882948
943887799	LM-Dental 887799
943888970	LM-Dental 888970

943898460	LM-Dental 898460
943902347	LM-Dental 902347
943902594	LM-Dental 902594
943906664	LM-Dental 906664
943911158	LM-Dental 911158
943913842	LM-Dental 913842
943914300	LM-Dental 914300
943918624	LM-Dental 918624
943920798	LM-Dental 920798
943929217	LM-Dental 929217
943931054	LM-Dental 931054
943932490	LM-Dental 932490
943938179	LM-Dental 938179
943940837	LM-Dental 940837
943944249	LM-Dental 944249
943944683	LM-Dental 944683
943951889	LM-Dental 951889
943955490	LM-Dental 955490
943961424	LM-Dental 961424
943962045	LM-Dental 962045
943975993	LM-Dental 975993
943983092	LM-Dental 983092
943983510	LM-Dental 983510
943994985	LM-Dental 994985
943998453	LM-Dental 998453
94100S	LM-Trainer Small
94100T	LM-Trainer Medium
94100T2	LM-Trainer 2 Medium
94100TB	LM-Trainer Braces
94025H	LM-Dental 486073
94030H	LM-Dental 915929
94035H	LM-Dental 578318
94010L	LM-Dental 283648
94015L	LM-Dental 153768
94020L	LM-Dental 661234
94030L	LM-Dental 904931
94035L	LM-Dental 618836
943286347	LM-Dental 286347
94020H	LM-Dental 591430
94040H	LM-Dental 475167
94025L	LM-Dental 794062
94010LS	LM-Activator 10LOW (short)
94015LS	LM-Activator 15LOW (short)
943110881	LM-Dental 110881
943119825	LM-Dental 119825
943137966	LM-Dental 137966
943140436	LM-Dental 140436
943149262	LM-Dental 149262
943153599	LM-Dental 153599
943167040	LM-Dental 167040

943186601	LM-Dental 186601
943198655	LM-Dental 198655
943217187	LM-Dental 217187
943235790	LM-Dental 235790
943251856	LM-Dental 251856
943261088	LM-Dental 261088
943270212	LM-Dental 270212
943274971	LM-Dental 274971
943277246	LM-Dental 277246
943294659	LM-Dental 294659
943297834	LM-Dental 297834
943313926	LM-Dental 313926
943347384	LM-Dental 347384
943391830	LM-Dental 391830
943441232	LM-Dental 441232
943454190	LM-Dental 454190
943473812	LM-Dental 473812
943475071	LM-Dental 475071
943476241	LM-Dental 476241
943489041	LM-Dental 489041
943503859	LM-Dental 503859
943525078	LM-Dental 525078
943528759	LM-Dental 528759
943534665	LM-Dental 534665
943540529	LM-Dental 540529
943569288	LM-Dental 569288
943591475	LM-Dental 591475
943593164	LM-Dental 593164
943631158	LM-Dental 631158
943644357	LM-Dental 644357
943658599	LM-Dental 658599
943673538	LM-Dental 673538
943673833	LM-Dental 673833
943687914	LM-Dental 687914
943696447	LM-Dental 696447
943709041	LM-Dental 709041
943724594	LM-Dental 724594
943748453	LM-Dental 748453
943752203	LM-Dental 752203
943752959	LM-Dental 752959
943760196	LM-Dental 760196
943762403	LM-Dental 762403
943767972	LM-Dental 767972
943781499	LM-Dental 781499
943798770	LM-Dental 798770
943799493	LM-Dental 799493
943805037	LM-Dental 805037
943849273	LM-Dental 849273
943875834	LM-Dental 875834
943895047	LM-Dental 895047

943905136	LM-Dental 905136
943905966	LM-Dental 905966
943912149	LM-Dental 912149
943940662	LM-Dental 940662
943944210	LM-Dental 944210
943968918	LM-Dental 968918
943974313	LM-Dental 974313
94435LS	My LM-Activator 35 Low Short
94440HS	My LM-Activator 40 High Short
94440LL	My LM-Activator 40 Low Long
94440LS	My LM-Activator 40 Low Short
94445HL	My LM-Activator 45 High Long
94445HS	My LM-Activator 45 High Short
94445LL	My LM-Activator 45 Low Long
94445LS	My LM-Activator 45 Low Short
94450HL	My LM-Activator 50 High Long
94450HS	My LM-Activator 50 High Short
94450LL	My LM-Activator 50 Low Long
94450LS	My LM-Activator 50 Low Short
94455HL	My LM-Activator 55 High Long
94455HS	My LM-Activator 55 High Short
94455LL	My LM-Activator 55 Low Long
94455LS	My LM-Activator 55 Low Short
94460HL	My LM-Activator 60 High Long
94460HS	My LM-Activator 60 High Short
94460LL	My LM-Activator 60 Low Long
94460LS	My LM-Activator 60 Low Short
94465HS	My LM-Activator 65 High Short
94465LL	My LM-Activator 65 Low Long
94465LS	My LM-Activator 65 Low Short
94470LS	My LM-Activator 70 Low Short

Appendix A, LM-OrthoSizer2

MDR Class I based on rule 5

LM-Orthosizer

Intended use: To aid in the selection of the appropriate size of a removable orthodontic device LM-Activator

Basic UDI 6438311ORTHOSIZER10GC

Code / Catalogue number	Trade name
9400	LM-OrthoSizer
9402	LM-Activator 2 OrthoSizer

Appendix A, instrument cassettes, trays and assessories

MDR Class I based on rule 1

Intended use: Device for storing dental instruments and protecting the instruments and users

Basic UDI 6438311CASSETTES10KT

Code / Catalogue number	Trade name
6410	ServoMax Tray Set, incl. 2 univ. trapper, 2 metal clips
6420	ServoMax standard case
6430	ServoMax restauration / endo case
6435	ServoMax foam, 20pcs
6450	ServoMax bur / endofile case
6460	ServoMax ultrasonic tip case
6471	ServoMax instrument rack,black (2pcs)
6472	ServoMax instrument rack,orang (2pcs)
6473	ServoMax instrument rack,blue (2pcs)
6474	ServoMax instrument rack,red (2pcs)
6475	ServoMax instrument rack,green (2pcs)
6490	ServoMax cup holder
6495	ServoMax Syringe holder
6551	Servo 5E, grey
6552	Servo 5E, blue
6553	Servo 5E, green
6554	Servo 5E, yellow
6581	Servo 8E, grey
6582	Servo 8E, blue
6583	Servo 8E, green
6584	Servo 8E, yellow
6650	LM-Servo 5 cassette
6680	LM-Servo 8 cassette
6551T	Servo 5E, grey DTS
6552T	Servo 5E, blue DTS
6553T	Servo 5E, green DTS
6554T	Servo 5E, yellow DTS
6581T	Servo 8E, grey DTS
6582T	Servo 8E, blue DTS
6583T	Servo 8E, green DTS
6584T	Servo 8E, yellow DTS
810001	Cassette for LM-LiftOut & LM-TwistOut
6415	ServoMax Metal Clips, 2pcs
6416	ServoMax Univ. Trapper, 2 pcs
6417	ServoMax lock for Servo 5E/8E

English (En-US)		
1	In the table the texts are in English, below you can find the translations when applicable	
2	Appendix	
3	Intended use: Dental hand instrument for diagnostic operations	
4	Intended use: Dental hand instrument for endodontic operations	
5	Intended use: Dental hand instrument for orthodontic operations	
6	Intended use: Dental hand instrument for restorative operations	
7	Intended use: Device for storing dental instruments and protecting the instruments and users	
8	Intended use: Removable orthodontic appliance	
9	MDR Class I based on rule 1	
10	MDR Class I based on rule 5	
11	Product code	
12	Basic UDI	
13	Code / Catalogue number	
14	Trade Name	
15	Revision	
16	Non-cutting restorative instruments	
17	Removable orthodontic appliance	
Bulgarian (BG)		
	В таблицата текстовете са на английски език, по-долу можете да откриете превод, ако е приложимо	
	Допълнение	
	Предвидена употреба Ръчен стоматологичен инструмент за диагностични процедури	
	Предвидена употреба Ръчен стоматологичен инструмент за ендодонтски процедури	
	Предвидена употреба Ръчен стоматологичен инструмент за ортодонтски процедури	
	Предвидена употреба Ръчен стоматологичен инструмент за възстановителни процедури	
	Предвидена употреба Изделие за съхранение на стоматологични инструменти и за предпазване на инструментите и ползвателите	
	Предвидена употреба Подвижен ортодонтски апарат	
	Клас I въз основа на правило 1 от Регламента за медицинските изделия	
	Клас I въз основа на правило 5 от Регламента за медицинските изделия	
	Код на продукта	
	Базов UDI	
	Код/каталоген номер	
	Търговско наименование	
	Редакция	
	Нережещи инструменти за възстановяване	
	Подвижен ортодонтски апарат	
Croatian (HR)		
	Tablica sadržiava tekstove na engleskom jeziku, u nastavku možete pronaći odgovarajuće prijevode	
	Prilog	
	Namjena: stomatološki ručni instrument za dijagnostičke postupke	
	Namjena: stomatološki ručni instrument za endodontske postupke	
	Namjena: stomatološki ručni instrument za ortodontske postupke	
	Namjena: stomatološki ručni instrument za restauracijske postupke	
	Namjena: proizvod za pohranu stomatoloških instrumenata i zaštitu instrumenata i korisnika	
	Namjena: mobilna ortodontska naprava	
	Medicinski proizvodi I. klase na temelju Pravila 1. Uredbe o medicinskim proizvodima	
	Medicinski proizvodi I. klase na temelju Pravila 5. Uredbe o medicinskim proizvodima	
	Kôd proizvoda	
	Osnovni UDI (Jedinstvena identifikacija proizvoda)	
	Šifra / kataloški broj	
	Trgovački naziv	
	Revizija	
	Instrumenti za restauraciju koji nisu namijenjeni za rezanje	
	mobilna ortodontska naprava	
Czech (CS)		
1	Text tabulky je v angličtině, příslušné překlady najdete níže	
2	Dodatek	
3	Účel použití: Ruční dentální nástroj pro diagnostické výkony	
4	Účel použití: Ruční dentální nástroj pro endodontické výkony	
5	Účel použití: Ruční dentální nástroj pro ortodontické výkony	
6	Účel použití: Ruční dentální nástroj pro záchovné výkony	
7	Účel použití: Zařízení pro skladování dentálních nástrojů a ochranu nástrojů a uživatelů	
8	Účel použití: Snímatelné ortodontické pomůcky	
9	MDR třída I podle pravidla 1	
10	MDR třída I podle pravidla 5	
11	Kód produktu	
12	Základní jedinečný identifikátor zdravotnického prostředku	
13	Kód / katalogové číslo	
14	Obchodní název	
15	Verze	
16	Nerezající záchovné nástroje	
17	Snímatelné ortodontické pomůcky	
Danish (DA)		
	Teksten er på engelsk i skemaet. Oversættelserne kan findes nedenfor, når det er relevant.	
	Bilag	
	Tilsigtet anvendelse: Tandkirurgisk håndinstrument til diagnostik	
	Tilsigtet anvendelse: Tandkirurgisk håndinstrument til endodonti	
	Tilsigtet anvendelse: Kirurgisk håndinstrument til ortodonti	
	Tilsigtet anvendelse: Tandkirurgisk håndinstrument til retableringsbrug	
	Tilsigtet anvendelse: Anordning til opbevaring af tandlægeinstrumenter og beskyttelse af instrumenterne og brugerne	
	Tilsigtet anvendelse: Aftagelig tandbøjle	
	MDR Klasse I baseret på regel 1	
	MDR-klasse I baseret på regel 5	
	Produktkode	
	Grundlæggende UDI	
	Kode/katalognummer	
	Handelsnavn	
	Revision	
	Ikke-skærende retableringsinstrumenter	
	Aftagelig tandbøjle	
Dutch (NL)		
	De tabel bevat Engelse teksten met indien van toepassing daaronder een vertaling	
	Bijlage	
	Beoogd gebruik: tandheelkundig handinstrument voor diagnostische ingrepen	
	Beoogd gebruik: tandheelkundig handinstrument voor endodontische ingrepen	
	Beoogd gebruik: tandheelkundig handinstrument voor orthodontische ingrepen	
	Beoogd gebruik: tandheelkundig handinstrument voor restauratieve ingrepen	
	Beoogd gebruik: hulpmiddel voor opslag van tandheelkundige instrumenten, beschermt instrumenten en gebruikers	
	Beoogd gebruik: verwijderbaar orthodontisch hulpmiddel	
	MDR-klasse I op basis van regel 1	
	MDR-klasse I op basis van regel 5	
	Productcode	
	Basis-UDI	
	Code/catalogusnummer	
	Handelsnaam	
	Herziening	
	Niet-snijdende restauratieve instrumenten	
	verwijderbaar orthodontisch hulpmiddel	
Estonian (ET)		
1	Tabelitekstid on inglise keeles, altpoolt leiata olemasolevad tõlked	
2	Lisa	
3	Sihtotstarve: hambaraviinstrument diagnostikatoimingute jaoks	
4	Sihtotstarve: hambaraviinstrument endodontiliste toimingute jaoks	
5	Sihtotstarve: hambaraviinstrument ortodontiliste toimingute jaoks	
6	Sihtotstarve: hambaraviinstrument resuratsioonitoimingute jaoks	
7	Sihtotstarve: seade hambaraviinstrumentide hoiustamiseks ja instrumentide ning kasutajate kaitsmiseks	
8	Sihtotstarve: eemaldatav ortodontiline vahend	
9	MDR-i klass I reegli 1 alusel	
10	MDR-i klass I reegli 5 alusel	
11	Tootekood	
12	Põhiline UDI	
13	Kood/katalooginumber	
14	Kaubanimi	
15	Redaktsioon	
16	Mitteloikavad restaureerimisinstrumentid	
17	eemaldatav ortodontiline vahend	
Finnish (FI)		
	Taulukon teksti on englanniksi, alla ovat soveltuvat käännökset	
	Liite	
	Käyttötarkoitus: Diagnostisissa toimenpiteissä käytettävä hammaslääketieteellinen käsikäyttöinen instrumentti	
	Käyttötarkoitus: Endodontisissa toimenpiteissä käytettävä hammaslääketieteellinen käsikäyttöinen instrumentti	
	Käyttötarkoitus: Ortodontisissa toimenpiteissä käytettävä hammaslääketieteellinen käsikäyttöinen instrumentti	
	Käyttötarkoitus: Paikkaustoimenpiteissä käytettävä hammaslääketieteellinen käsikäyttöinen instrumentti	
	Käyttötarkoitus: Laite hammaslääketieteellisten instrumenttien säilytykseen ja instrumentin ja käyttäjien suojaamiseen	
	Käyttötarkoitus: Poistettavat oikomiskojeet	
	Luokan I lääkinällinen laite säännön 1 mukaan	
	Luokan 1 lääkinnällinen laite säännön 5 mukaan	
	Tuotekoodi	
	Yksilöllinen laitetunniste	
	Koodi/luettelonumero	
	Kauppanimi	
	Versio	
	Leikkaamattomat paikkausinstrumentit	
	Poistettavat oikomiskojeet	
French (FR)		
	Les textes sont en anglais dans le tableau. Vous trouverez ci-dessous les traductions, le cas échéant	
	Annexe	
	Usage prévu : Instrument dentaire à main pour opérations diagnostiques	
	Usage prévu : Instrument dentaire à main pour opérations d'endodontie	
	Usage prévu : Instrument dentaire à main pour opérations d'orthodontie	
	Usage prévu : Instrument dentaire à main pour opérations de restauration	
	Usage prévu : Dispositif destiné au stockage d'instruments dentaires et à la protection des instruments et des utilisateurs	
	Usage prévu : Appareil orthodontique amovible	
	RDM de classe I d'après la règle 1	
	RDM de classe I d'après la règle 5	
	Code du produit	
	IUD de base	
	Code / Numéro de catalogue	
	Nom commercial	
	Révision	
	Instruments de restauration non tranchants	
	Appareil orthodontique amovible	

German (DE)		Greek (EL)	Hungarian (HU)
1	Die Tabelle ist auf Englisch. Übersetzungen finden sich, soweit vorhanden, unten.	Στον πίνακα τα κείμενα είναι στα Αγγλικά. Παρακάτω μπορείτε να βρείτε τις μεταφράσεις κατά περίπτωση.	A táblázatban a szövegek angol nyelven szerepelnek, a fordításokat adott esetben alatta találja.
2	Anhang	Παράρτημα	Függelék
3	Verwendungszweck: Zahnmedizinisches Handinstrument zur Diagnostik	Προβλεπόμενη χρήση: Οδοντιατρικό εργαλείο χειρός για διαγνωστικές επεμβάσεις	Rendeltetésszerű használat: Fogászati kézi műszer diagnosztikus műtétekhez
4	Verwendungszweck: Zahnmedizinisches Handinstrument für endodontologische Eingriffe	Προβλεπόμενη χρήση: Οδοντιατρικό εργαλείο χειρός για ενδοδοντικές επεμβάσεις	Rendeltetésszerű használat: Fogászati kézi műszer endodontikus műtétekhez
5	Verwendungszweck: Zahnmedizinisches Handinstrument für orthodontische Eingriffe	Προβλεπόμενη χρήση: Οδοντιατρικό εργαλείο χειρός για ορθοδοντικές επεμβάσεις	Rendeltetésszerű használat: Fogászati kézi műszer fogszabályozási műtétekhez
6	Verwendungszweck: Zahnmedizinisches Handinstrument für Restaurationen	Προβλεπόμενη χρήση: Οδοντιατρικό εργαλείο χειρός για επεμβάσεις αποκατάστασης	Rendeltetésszerű használat: Fogászati kézi műszer helyreállító műtétekhez
7	Verwendungszweck: Gerät zum sicheren Aufbewahren zahnmedizinischer Instrumente und zum Schutz von Anwendern	Προβλεπόμενη χρήση: Συσκευή αποθήκευσης οδοντιατρικών εργαλείων και προστασίας των εργαλείων και των χρηστών	Rendeltetésszerű használat: Eszköz a fogászati műszerek tárolására, valamint a műszerek és felhasználók védelmére
8	Verwendungszweck: Abnehmbare orthodontische Geräte	Προβλεπόμενη χρήση: Αφαιρούμενη ορθοδοντική συσκευή	Rendeltetésszerű használat: Eltávolítható fogszabályozó készülék
9	Verordnung über Medizinprodukte, Klasse I nach Regel 1	Κανονισμός για τα ιατροτεχνολογικά προϊόντα, Κατηγορία I, σύμφωνα με τον Κανόνα 1	MDR I. osztály az 1. szabály alapján
10	Verordnung über Medizinprodukte, Klasse I nach Regel 5	Κανονισμός για τα ιατροτεχνολογικά προϊόντα, Κατηγορία I, σύμφωνα με τον Κανόνα 5	MDR I. osztály az 5. szabály alapján
11	Produktcode	Κωδικός προϊόντος	Termékkód
12	Basis-UDI	Βασικό UDI	Alapvető UDI
13	Code/Katalognummer	Κωδικός / Αριθμός καταλόγου	Kód / katalógusszám
14	Handelsname	Εμπορική ονομασία	Kereskedelmi név
15	Fassung	Αναθεώρηση	Felülvizsgálat
16	Restaurationsinstrumente ohne Schneidfunktion	Μη κοπτική εργαλεία αποκατάστασης	Nem vágó helyreállító műszerek
17	Abnehmbare orthodontische Geräte	Αφαιρούμενη ορθοδοντική συσκευή	Eltávolítható fogszabályozó készülék
Polish (PL)		Portuguese (PT)	Romanian (RO)
1	Teksty w tabelce są w języku angielskim; poniżej znajdują się tłumaczenia (jeśli występują)	Na tabela, os textos estão em inglês; em baixo poderá encontrar as traduções, quando aplicável	Textele cuprinse în tabel sunt în limba engleză, traduceri le acestora sunt disponibile mai jos, după caz
2	Załącznik	Anexo	Anexă
3	Przeznaczenie: Ręczne narzędzie stomatologiczne do zabiegów diagnostycznych	Utilização pretendida: Instrumento odontológico manual para operações de diagnóstico	Utilizarea propusă: Instrument stomatologic de mână pentru proceduri de diagnostic
4	Przeznaczenie: Ręczne narzędzie stomatologiczne do zabiegów endodontycznych	Utilização pretendida: Instrumento odontológico manual para operações endodônticas	Utilizarea propusă: Instrument stomatologic de mână pentru proceduri endodontice
5	Przeznaczenie: Ręczne narzędzie stomatologiczne do zabiegów ortodontycznych	Utilização pretendida: Instrumento odontológico manual para operações ortodônticas	Utilizarea propusă: Instrument stomatologic de mână pentru proceduri ortodontice
6	Przeznaczenie: Ręczne narzędzie stomatologiczne do zabiegów odwrótczych	Utilização pretendida: Instrumento odontológico manual para operações de restauração	Utilizarea propusă: Instrument stomatologic de mână pentru proceduri de obturație
7	Przeznaczenie: Urządzenie do przechowywania narzędzi stomatologicznych i ochrony narzędzi i użytkowników	Utilização pretendida: Dispositivo para guardar instrumentos odontológicos e para proteção dos instrumentos e utilizadores	Utilizarea propusă: Dispozitiv pentru depozitarea instrumentelor stomatologice și pentru protejarea instrumentelor și a utilizatorilor
8	Przeznaczenie: Usuwalny aparat ortodontyczny	Utilização pretendida: Removedor de aparelho ortodôntico	Utilizarea propusă: Aparat ortodontic detașabil
9	Klasa I rozporządzenia w sprawie wyrobów medycznych wg reguły 1	MDR Classe I com base na regra 1	Clasa I în conformitate cu norma 1 din Regulamentul privind dispozitivele medicale (MDR)
10	Klasa I rozporządzenia w sprawie wyrobów medycznych wg reguły 5	MDR Classe I com base na regra 5	Clasa I în conformitate cu norma 5 din Regulamentul privind dispozitivele medicale (MDR)
11	Kod produktu	Código do produto	Codul produsului
12	Podstawowy UDI	UDI básica	UDI de bază
13	Kod / numer katalogowy	Código/Número do catálogo	Cod/număr de catalog
14	Nazwa handlowa	Designação comercial	Denumire comercială
15	Wersja	Revisão	Revizie
16	Nieinwazyjne narzędzia do stomatologii odwrótczej	Instrumentos de restauração não cortantes	Instrumente de obturație fără incizie
17	Usuwalny aparat ortodontyczny	Removedor de aparelho ortodôntico	Aparat ortodontic detașabil
Italian (IT)		Latvian (LV)	Lithuanian (LT)
1	Il testo della tabella è in lingua inglese, di seguito sono disponibili le traduzioni, ove applicabili	Teksts tabulā ir angļu valodā, tālāk varat skatīt tulkojumus (ja attiecas)	Tekstas lentelėje yra anglų kalba, toliau pateikiamas vertimas, jei taikoma.
2	Appendice	Pielikums	Priedas
3	Uso previsto: Strumento dentale manuale per operazioni diagnostiche	Paredzētais lietojums: dentālais rokas instruments diagnostikai	Paskirtis: rankinis instrumentas diagnostinėms dantų procedūroms
4	Uso previsto: Strumento dentale manuale per operazioni endodontiche	Paredzētais lietojums: dentālais rokas instruments endodontiskām darbībām	Paskirtis: rankinis instrumentas endodontinėms procedūroms
5	Uso previsto: Strumento dentale manuale per operazioni ortodontiche	Paredzētais lietojums: dentālais rokas instruments ortodontiskām darbībām	Paskirtis: rankinis instrumentas ortodontinėms procedūroms
6	Uso previsto: Strumento dentale manuale per operazioni di conservativa	Paredzētais lietojums: dentālais rokas instruments restaurācijas darbībām	Paskirtis: rankinis instrumentas dantų restauracinėms procedūroms
7	Uso previsto: Dispositivo per la conservazione degli strumenti dentali e la protezione di strumenti e utenti	Paredzētais lietojums: ierīce dentālo instrumentu glabāšanai un instrumentu un lietotāju aizsardzībai	Paskirtis: priemonė odontologiniams instrumentams laikyti ir instrumentams ir naudotojams apsaugoti
8	Uso previsto: Apparecchio ortodontico rimovibile	Paredzētais lietojums: noņemama ortodontiska ierīce	Paskirtis: nuimamas ortodontijos prietaisas
9	Regolamento sui dispositivi medici di Classe I in base alla norma 1	Medicīnisko ierīču regulā noteiktā I klase atbilstoši 1. noteikumam	1 klases pagal Medicinos priemonių reglamento 1 taisyklę
10	Regolamento sui dispositivi medici di Classe I in base alla norma 5	Medicīnisko ierīču regulā noteiktā I klase atbilstoši 5. noteikumam	1 klases pagal Medicinos priemonių reglamento 5 taisyklę
11	Codice del prodotto	Produkta kods	Gaminio kodas
12	Basic UDI	Pamata UDI	Bazinis UDI
13	Codice/numero di catalogo	Kods/numurs katalogā	Kodas / katalogo numeris
14	Denominazione commerciale	Tirdzniecības nosaukums	Prekybinis pavadinimas
15	Revisione	Pārskatītā versija	Peržiūra
16	Strumenti per conservativa che non richiedono affilatura	Restaurācijas instrumenti, kas nav paredzēti griešanai	Nepjaunamieji instrumentai restauracijoms
17	Apparecchio ortodontico rimovibile	noņemama ortodontiska ierīce	nuimamas ortodontijos prietaisas

Slovak (SK)

- 1 V tabulke sú texty v angličtine, nižšie nájdete prípadne preklady
- 2 Dodatok
- 3 Určené použitie: Zubársky ručný nástroj na diagnostické zákroky
- 4 Určené použitie: Zubársky ručný nástroj na endodontické zákroky
- 5 Určené použitie: Zubársky ručný nástroj na ortodontické zákroky
- 6 Určené použitie: Zubársky ručný nástroj na restoratívne zákroky
- 7 Určené použitie: Zariadenie na uchovávanie zubárskych nástrojov a ochranu nástrojov a používateľov
- 8 Určené použitie: Odstrániteľné ortodontické nástroje
- 9 MDR trieda I na základe pravidla 1
- 10 MDR trieda I na základe pravidla 5
- 11 Kód produktu
- 12 Podstawowy UDI
- 13 Kod / numer katalogowy
- 14 Nazwa handlowa
- 15 Wersja
- 16 Nerežúce restoratívne nástroje
- 17 Odstrániteľné ortodontické nástroje

Swedish (SV)

- 1 I tabellen finns texterna på engelska, nedan kan du hitta översättningarna när det är tillämpligt
- 2 Bilaga
- 3 Avsedd användning: Dentalhandinstrument för diagnostiska arbeten
- 4 Avsedd användning: Dentalhandinstrument för endodontiska arbeten
- 5 Avsedd användning: Dentalhandinstrument för ortodontiska arbeten
- 6 Avsedd användning: Dentalhandinstrument för återställande operationer
- 7 Avsedd användning: Enhet för förvaring av tandinstrument och skydd av instrument och användare
- 8 Avsedd användning: Avtagbar ortodontisk apparat
- 9 MDR klass I baserat på regel 1
- 10 MDR klass I baserat på regel 5
- 11 Produktkod
- 12 Grundläggande UDI
- 13 Kod / Katalognummer
- 14 Handelsnamn
- 15 Revision
- 16 Icke-skärande återställande instrument
- 17 Avtagbar ortodontisk apparat

Slovenian (SL)

- Besedila v tabeli so v angleščini, v nadaljevanju lahko najdete prevode.
- Dodatek
- Predvidena uporaba: zobozdravstveni ročni instrument za diagnostične operacije
- Predvidena uporaba: zobozdravstveni ročni instrument za endodontske operacije
- Predvidena uporaba: zobozdravstveni ročni instrument za ortodontske operacije
- Predvidena uporaba: zobozdravstveni ročni instrument za restavracijske operacije
- Predvidena uporaba: pripomoček za shranjevanje zobozdravstvenih instrumentov ter zaščito instrumentov in uporabnikov
- Predvidena uporaba: snemljiv ortodontski pripomoček
- Uredba o medicinskih pripomočkih razreda I na osnovi pravila 1
- Uredba o medicinskih pripomočkih razreda I na osnovi pravila 5
- Koda izdelka
- UDI bázica
- Código/Número do catálogo
- Designação comercial
- Revisão
- Restavracijski instrumenti brez rezila
- snemljiv ortodontski pripomoček

Spanish (ES)

- En la tabla aparece el texto en inglés. A continuación, encontrará las traducciones cuando proceda
- Apéndice
- Uso previsto: instrumento dental manual para operaciones de diagnóstico
- Uso previsto: instrumento dental manual para operaciones de endodoncia
- Uso previsto: instrumento dental manual para operaciones de ortodoncia
- Uso previsto: instrumento dental manual para operaciones de reparación
- Uso previsto: dispositivo para almacenar instrumental odontológico y proteger los instrumentos y a los usuarios
- Uso previsto: aparato de ortodoncia extraíble
- Reglamento sobre dispositivos médicos de clase I basado en la regla 1
- Reglamento sobre dispositivos médicos de clase I basado en la regla 5
- Código de producto
- Grundläggande UDI
- Kod / Katalognummer
- Handelsnamn
- Revision
- Instrumentos no cortantes para la reparación
- aparato de ortodoncia extraíble