QUALITY MANAGEMENT SYSTEM

EU-CERTIFICATE

Regulation (EU) 2017/745

Manufacturer:	LM-Instruments Oy Norrbyn rantatie 8 21600 Parainen Finland
Single registration number:	FI-MF-000006705
Conformity assessment procedure:	Regulation (EU) 2017/745 Annex IX
Device category:	MDN 1208 Non-active non-implantable instruments
Date of expiry:	11 September 2028

The manufacturer's quality management system covering the device category been assessed and approved in accordance with the Annex IX to Regulation (EU) 2017/745. Approval shall be valid until the expiry date provided that the manufacturer fulfills the obligations imposed by Annex IX in Regulation. The products covered by the certificate and the details related to the maintenance of this certificate are specified in the attachment to the certificate.

Date of issue: 11 September 2023

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Certificate no:

CR-03-1080-826-23

Notified Body no. 0537:
Eurofins Electric & Electronics Finland Oy
Kivimiehentie 4
FI-02151 Espoo, FINLAND

Information about the examinations and tests as per MDR Annex XII, section 10, is available upon request from EES-medical@eurofins.fi.

Attachment 1 to the certificate no: CR-03-1080-826-23

Manufacturer:	LM-Instruments Oy Norrbyn rantatie 8 21600 Parainen Finland
Other sites covered by the quality management system:	-
Single registration number:	FI-MF-000006705
Conformity assessment procedure:	Regulation (EU) 2017/745 Annex IX
Limitations to the validity of the certificate:	No limitations

The certificate covers the following products:

MD-codes:	MDN 1208 MDS 1006 MDT 2001, MDT 2002, MDT 2011	
Device category:	MDN 1208 Non-active non-implantable instruments	
Product name	*Product details*	
Periodontal hand instruments	Model	-
	Nomenclature code	L159001 Dental and periodontal curettes, reusable
	Risk class	Ir

For class Im/Is/Ir devices quality management system has been audited limiting only to the aspects required under the article 52(7).

The validity and maintenance of this certificate require the surveillance performed by the notified body in accordance with the MDR Annex IX (3). The surveillance includes annual quality management system audits at the manufacturer's premises as well as regular unannounced audits. If necessary, all audits may be carried out at the premises of the manufacturer's suppliers and/or subcontractors. The surveillance also includes the assessment of the significant changes planned by the manufacturer and the assessment of the technical documentation in accordance with the notified body's sampling plan (IIa and IIb).

Attachment 1 to the certificate no: CR-03-1080-826-23

Date of issue of this attachment: 11 September 2023

Aliisa Siljander

Tiia Tuokko

Change history of the certificate:				
Certificate no	**Revision**	**Status of the certificate**	**Date of issue**	**Description of the change**
CR-03-1080-826-23	01	Initial certification	11.9.2023	Initial revision