

DECLARATION OF CONFORMITY

EC COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES

Manufacturer:

LM-Instruments Oy

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Finland

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Herewith we declare that the below mentioned products equipped with original accessories comply with the relevant regulations of the guideline 93/42/EEC for medical devices as they have been modified with the directive 2007/47/EC with reference to the following harmonized standards: IEC 60601-1:2005/AMD1:2012, IEC 60601-1-2:2014 Edition 4.0, IEC 60601-1-6:2010+A1:2015 and IEC 80601-2-60:2012

THE PRODUCTS:

Polisher nozzles

LM-ProPower CombiLED 10075, 10075JP, 10075US, 1007375 LM-ProPower Ultra, Built-in 15610881 15611171 15611181 156

LM-ProPower Ultra, Built-in 15610881, 15611171, 15611181, 15611191 LM-ProPower Ultra Std, Built-in 15607442, 15610931, 15610941, 15610951

LM-ProPower Ultra Std, Built-in 15607442, 15610931, 15610941, 1561098 LM-ProPower UltraLED, Built-in 15610861, 15611231, 15611241

LM-ProPower UltraLED Std, Built-in 15610961, 15610971, 15610981 Scaler Tips

Classification: Medical Devices, Class Ila.

EC Certificate for quality system: issued by Eurofins Expert Services Oy, Medical Devices; Notified Body number 0537

Date, place: 23.1.2020, Parainen

Kari Lehtonen

Quality and Development Manager

LM-Instruments Oy