Declaration number: 5-2020

EC DECLARATION OF CONFORMITY

Manufacturer: PRIZMA KRAGUJEVAC d.o.o.
Kumanovska street 8,
34000 Kragujevac, SERBIA

Place of Manufacture: PRIZMA KRAGUJEVAC d.o.o.
Dr Zorana Đinđića street 13,
34000 Kragujevac, SERBIA

European Representative: GRAJSKA VRATA d.o.o
Šmiklavž 3a,
3324 Gornji Grad, SLOVENIA

Product name: PRIZMA ultrasonic nebuliser

Model /Type: PROFI SONIC H

Classification: Class IIa (MDD Annex IX, Rule 11)

We, as manufacturer, declare under sole responsibility that the mentioned product are fully complying with the essential requirements of Directive 93/42/ECC of medical devices.

The product was a subject of conformity assessment procedure described in Annex II (Full quality assurance system) excluding the point 4 of Annex II.

We, as manufacturer, declare under sole responsability that the mentioned product are fully complyingwith requirements of Directives 2011/65/EU - Restriction of the use of certain hazardous substances (RoHS) and 2012/19/EU - Directive on waste electrical and electronic equipment (WEEE)

General applicable directives: MDD - 93/42/EEC, RoHS - 2011/65/EU , WEEE - 2012/19/EU

Standards applied:

EN 60601-1:2006+A1:2013+A12:2014	
EN 60601-1-2:2015	
EN 60601-1-6:2010+A1:2015	EN 62366:2008
EN 62304:2006/AC:2008	EN 15223-1:2016
EN 1041:2008	EN ISO 14971:2012
EN 13544-1:2007/A1:2009	EN 10993-1:2009/AC:2010
EN ISO 10993-5:2009	ISO 10993-10:2010

Notified Body: SIQ, Slovenian Institute of Quality and Metrology
Tržaška cesta 2
1000 Ljubljana, SLOVENIA
Notified Body No. 1304

EC Certificate: No: MDD-006
Certification date: 12.11.2009.
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Valid until: 27.05.2024.

Place / Date: Kragujevac / 01.04.2020.

Signature:

Name/ Position: Mihajlo Miletić / QA