



DECLARATION OF CONFORMITY

According to ISO/IEC/EN17050

Manufacturer's Name : Mediana Co., Ltd.
Manufacturer's Address : 132, Donghwagongdan-ro, Munmak-eup,
Wonju-si, Gangwon-do, Korea
EU representative : OBELIS S.A
Bd. Général Wahis, 53, 1030 Brussels, Belgium

Declares with sole responsibility of the manufacturer, that the product

Product Common Name : AUTOMATED EXTERNAL DEFIBRILLATOR
Reference : HeartOn A16-DS / HeartOn A16-DF / HeartOn A16-GS
/ HeartOn A16-GF
Product Model Name(s) : HeartOn A16-DS / HeartOn A16-DF / HeartOn A16-GS
/ HeartOn A16-GF

Further description of the device and modules are given in instruction manual.

Classification / Rule : Class IIb / Rule 9
GMDN : HeartOn A16-DS, HeartOn A16-GS
48049 (Non-rechargeable professional semi-automated
external defibrillator),
47910 (Non-rechargeable public semi-automated
external defibrillator)
HeartOn A16-DF, HeartOn A16-GF
48047 (Non-rechargeable public automated external
defibrillator)

Conformity Assessment Route : Annex II excl. section 4

Supplementary Information

The above product(s)

complies (comply) with the applicable requirements of Medical Device Directive, 93/42/EEC as amended by 2007/47/EC of 21 September 2007 and bear(s) the CE-marking accordingly.

is (are) subject to the procedure set out in Annex II excl. section 4 of Directive 93/42/EEC as amended by 2007/47/EC under the supervision of Notified Body 2797, BSI Group The Netherlands B.V., Say Building John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands.

26 October, 2020
Originally signed in Seoul Korea,
on 15 November, 2019

Dongwon Kang, Vice President

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