



DECLARATION OF CONFORMITY  
According to ISO/IEC/EN17050-1

**Manufacturer's Name** : Mediana Co., Ltd.  
**Manufacturer's Address** : 132, Donghwagongdan-ro,  
Munmak-eup, Wonju-si, Gangwon-do, 26365,  
Republic of Korea  
**EU representative** : OBELIS S.A  
Bd. Général Wahis, 53, 1030 Brussels, Belgium  
**CE Certificate Number** : CE 691292

**Declares with sole responsibility of the manufacturer, that the product**

Product Common Name : AUTOMATED EXTERNAL DEFIBRILLATOR  
Reference : HeartOn A15<sup>®</sup>  
Product Model Name(s) : HeartOn A15<sup>®</sup> (8 action icon of HeartOn A15)  
HeartOn A15-G4<sup>®</sup> (4 action icon of HeartOn A15)

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

Classification / Rule : IIb / Rule 9  
GMDN : 48049 (Non-rechargeable professional semi-automated external defibrillator),  
47910 (Non-rechargeable public semi-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, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands.

**03 June, 2021**

Originally signed in Seoul Korea,  
on 15 March, 2013

**Dongwon Kang, President**

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<u>2021.06.03</u>	MDR-CC130212-03	<u>9</u>	