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Directive to which conformity is declared: **93/42/EEC Annex II excl. section 4 - Medical Device Directive and amendment 2007/47/EC on Medical Device.**

Application of the Standards:
EN 60601-1:2006 / A1:2013
EN 60601-1-2:2015
EN 60601-1-6:2010
EN 60601-1-8:2007 / AC:2010
IEC 60601-2-4:2010
IEC 62304:2015
EN 62366:2008
EN ISO 14971:2012
EN ISO 13485:2016
EN ISO 10993-1:2009/AC:2010
EN ISO 10993-5:2009
ISO 10993-10:2010

Manufacturer's name: **Instramed Indústria Médico Hospitalar LTDA.**
Manufacturer's address: **Beco José Paris 339/19, Porto Alegre, RS - Brazil**

Authorized Representative name: **Obelis S.A.**
Authorized Representative address: **Bd. Général Wahis 53, 1030 Brussels - Belgium**

Type of equipment: **Automated External Defibrillator**

Trade mark / Model: **i.on and i.on Pro**

Accessories:

- **Power source internal battery charger – Class II, Code 79051;**
- **CPR Maestro – Code 11066 (Optional);**
- **Multifunctional Adhesive Pads – Code 79047;**
- **5 leads ECG Cable – Code 79005 – Class I, third party.**

Classification: **Class IIb in compliance with Rule 9 of annex IX of the directive 93/42/EEC.**

Notified body: **DNV GL Presafe AS**
Veritasveien 3, 1363 Høvik, Norway
CE 2460

We, the undersigned, hereby declare that equipment specified above conforms to the above Directives and Standards

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Porto Alegre, December 02, 2020.

Arthur J. A. Moraes
General Manager
Instramed

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