



EC DECLARATION OF CONFORMITY

Manufacturer's name: **FREY Sp.J.**
05-502 Piaseczno; ul. Wołodziejowskiego 38;
Poland

Identification of device: Automated Perimeter
Model No.: AP-300
Classification: I with measuring function
Starting from this serial number: OBDH001K

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentation are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

Medical Device Directive : COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices

Standards :

Harmonized Standards (published in the Official Journal of the European communities) applicable to this products are :

- EN 60601-1:2006 +A11:2011 +A1:2013 (PN-EN 60601-1:2011 +A11:2011 +A1:2014)
- EN 60601-1-2:2015 (PN-EN 60601-1-2:2015)
- EN 62304:2006/AC:2008 (PN-EN 62304:2010)
- EN ISO 10993-1:2009 (PN-EN ISO 10993-1:2010)
- EN ISO 14971:2012 (PN-EN ISO 14971:2012)
- EN ISO 15004-1:2009 (PN-EN ISO 15004-1:2010)
- EN ISO 15223-1:2016 (PN -EN ISO 15223-1:2017-02)

Conformity assessment according to Annex 5 of Directive 93/42/EEC was performed with the involvement of Notified Body No 1434 – Polish Centre for Testing and Certification S.A., 23A Kłobucka Street, 02-699 Warsaw.

Obtained the Certificate of Conformity No 1434-MDD-057/2018 Annex No. 1

Piaseczno 2019-01-02


Wojciech Frey
Managing Director