Manufacturer
UAB „Medinstrus”
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EU DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

acc. to Article 19 of Regulation (EU) 2017/745 on Medical Devices

On our sole responsibility, we hereby declare that the product(s)

Equipment type: **Refraction Unit**

Model: **MASTER**

Type: **BETA**

(Basic UDI 477905507MASTERQ3)

comply with the relevant provisions of the following Regulation(s) and Directive(s), **harmonised standards**:

2014/30/EU	DIRECTIVE 2014/30/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast)
2011/65/EU	Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast) Text with EEA relevance
2017/745 EU	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.)
EN 60601-1:2006	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance EN 60601-1:2006 (including IEC 60601-1:2005/A1:2012; IEC 60601-1:2005/A2:2020; EN 60601-1:2006/AC:2010; EN 60601-1:2006/A12:2014; EN 60601-1:2006/A1:2013/AC:2014;
ISO 14971:2019	Medical devices — Application of risk management to medical devices ISO 14971:2019

Classification (acc. to Annex VIII of MDR): According to Rule 13, Class I.

We herewith declare that the above mentioned products,
- Do not contain a CMR (substances which are carcinogenic, mutagenic or toxic to reproduction (‘CMR’) and/or endocrine-disrupting substances,
- Do not contain a phthalates,
- Do not contain materials of biological origin of human or animal origin,
- Do not contain nanomaterial.

The declaration of conformity is prepared based on the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices.

Date of issue 2023-11-27
Place Mažeikiai, Lithuania

Signed on behalf of UAB Medinstrus
CEO Vitalis Balčytis