EU Declaration of Conformity

PULS GmbH declares under our sole responsibility that the equipment named below is in conformity with the requirements of the following European directives and their delegated directives:

2014/35/EU (LVD)
Directive 2014/35/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 the making available on the market of electrical equipment designed for use within certain voltage limits.

2014/30/EU (EMC)
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.

2011/65/EU (RoHS)
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

Equipment:

CP20.241-M1

The following standards were used to assess the equipment:

EN 60601-1:2006 / A1:2013 Medical electrical equipment — Part 1: General requirements for basic safety and essential performance

EN 61000-6-1:2007 and EN IEC 61000-6-1:2019 Generic immunity standard for residential environments

EN 61000-6-2:2005 / AC:2005 and EN IEC 61000-6-2:2019 Generic immunity standard for industrial environments

EN 61000-6-3:2007 / A1:2011 / AC:2012 Generic emission standard for residential environments

EN 61000-6-4:2007 / A1:2011 and EN IEC 61000-6-4:2019 Generic emission standard for industrial environments

EN IEC 63000:2018 Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

Manufacturer:
PULS GmbH, Elektrastr. 6, 81925 Munich, Germany

Additional information:
-The safety requirements of the medical device standard EN 60601-1 are stricter than the safety requirements of typical harmonized standards for the Directive 2014/35/EU (LVD). Therefore, the safety objectives of the Directive 2014/35/EU are considered to be fulfilled.
-The equipment also meets the requirements for 2MOPP (two means of patient protection) for medical applications in accordance with IEC 60601-1

Vienna, 2022-04-19

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Ewald Braith
Managing Director Puls Vario GmbH
Authorized representative for PULS GmbH