# 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:**

**CP10.241-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

Additional information:
The safety requirements of the medical device standard EN/IEC 60601-1 are stricter than the safety requirements of typical harmonized standards for the LVD Directive 2014/35/EU. Therefore the safety objectives of the LVD 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.

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

Vienna, 2026-07-16

*This is the internet version of the EU Declaration of Conformity which bears no signature but contains the same informations as the signed document. If a copy of a declaration with an actual signature should be needed, please contact your local PULS sales office.*

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

# EU Declaration of Conformity

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

**(EU) 2025/40** (PPWR)
of 19 December 2024 on packaging and packaging waste, amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904, and repealing Directive 94/62/EC

**Packaging ID:**

**CP10.241-M1-PACKAGING**

The purpose of the packaging is to serve as primary packaging for the product.

References to the relevant harmonised standards or the common specifications used or references to the other technical specifications in relation to which conformity is declared:

**(EU) 2025/40** Article 5: Requirements for substances in packaging

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

Vienna, 2026-07-16

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