



EC Declaration of Conformity



Name of medical product: **CardioNS E2**

REF No.: CE2

Manufacturer: **Panonit d.o.o. Novi Sad**

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This declaration of conformity is issued under the sole responsibility of the Panonit d.o.o. Novi Sad.

Object of the declaration

Medical Product:	CardioNS E2
GMDN Code:	62641
Classification:	Class IIa
MDD rule:	MDD 93/42/EEC, Annex IX, Rule 10

We, Panonit ensure and declare under our sole responsibility that the listed product CardioNS E2 to which this Declaration of Conformity relates are in conformity and meet the provisions of EC Directive 93/42/EEC, as amended per MDD 2007/47/EC, which apply to them and covered by CE mark with Notification Number: 1 304 from Notification Body: Slovenian Institute of Quality and Metrology - **SIQ**, Mašera - Spasićeva 10, 1000 Ljubljana, Slovenia.

CardioNS E2 has been classified as Class IIa, according to Annex IX and are in conformity with the essential requirements and provisions of the Council Directive 93/42/EEC concerning medical devices. The product is subject to the procedure set out in Annex II of the Council Directive 93/42/EEC.

Conformity assessment route: According to Annex II (full quality assurance).

Applied harmonized standards: ISO 15223-1:2016, EN ISO 15223-1:2016, EN 1041:2008/A1:2013, EN ISO 14971:2012, IEC 62366-1:2015, IEC 62304:2006/A1:2015, ISO 11073-91064:2009, ISO 11240:2012, EN 60601-1:2006/A1:2013, EN 60601-1-2:2015, EN 60601-1-6:2010, EN 60601-1-11:2010, IEC 60601-2-25:2011, EN ISO 10993-1:2009/AC:2010.

This declaration is made on base of the EC Certificate, certificate number: MDD-205 delivered by Notified Body No 1304, Slovenian Institute of Quality and Metrology - **SIQ**, Mašera - Spasićeva 10, 1000 Ljubljana, Slovenia.

This declaration is valid until 31.12.2028.

Signed for and on behalf of: Panonit d.o.o. Novi Sad

Director, Srđan Sladojević (signature)

Place and Date: Novi Sad, Serbia, 24.05.2024.