

PAUL HARTMANN AG
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Heidenheim, 2016-12-21

EU-Declaration of Conformity acc. to Directive 2011/65/EU (RoHS)

1. Product name:

VivanoTec Pro

2. Name and address of the manufacturer:

PAUL HARTMANN AG
Paul-Hartmann-Straße 12
89522 Heidenheim, Germany

3. This declaration of conformity is issued under the sole responsibility of the manufacturer:

PAUL HARTMANN AG

4. Object of the declaration (short description):

Negative pressure unit

5. The object of the declaration described above is in conformity with 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 (*).

6. Where applicable, references to the relevant harmonised standards used or references to the technical specifications in relation to which conformity is declared:

- EN 50581

7. Additional information (if applicable):

PAUL HARTMANN AG

Dr. W. Neumann
Chief Medical Officer

ppa.

Dr. A. Eckle
Director Regulatory Affairs

Are further regulations requiring an EC-declaration of conformity applicable to the above mentioned product(s)?

☐ no

☒ yes: EU Regulation/Directive 93/42/EEC concerning medical devices

(*) OJ L 174, 1.7.2011, p. 88.

IILN 040 9500 00000 0

Vorstand/ Management Board: Andreas Joehle
(Vorstandsvorsitzender/ CEO). Dr. Raymund Heinen.
Michel Kuehn. Dr. Wolfgang Neumann. Stephan Schulz.
Aufsichtsratsvorsitzender/ Chairman of the Supervisory Board:
Fritz-Jürgen Heckmann

Sitz Heidenheim
Amtsgericht Ulm HRB 661090
Registered Office Heidenheim
Commercial Register of the District Court of Ulm file no. HRB 661090