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HARTMANN
Going further for health

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

ppa.

Dr. W. Neumann
Chief Medical Officer

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.