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HARTMANN

Going further for health

EC-Declaration of Conformity for Medical Device Class 1 and Personal Protective Equipment

Heidenheim, 2019-09-24

We herewith declare,

Object of the declaration: **Peha-soft nitrile white**
Peha-soft nitrile fino

which have been first placed on the market by PAUL HARTMANN AG, meet the applicable provisions, especially the essential requirements of the following EU-legislation:

- **Council Directive 93/42/EEC for medical devices (MDD)**
- **Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment**

The required conformity assessment procedure according to MDD Annex VII has been performed and the technical documentation is kept available.
This EC-Declaration of Conformity is issued under the sole responsibility of the PAUL HARTMANN AG.

Medical Device: Class 1 acc. to rule 5 (1st)

(acc. to Annex IX of the directive)

UMDNS: 11-882

For Personal Protective Equipment Regulation:

IILN 040 9500 00000 0

Vorstand/ Management Board: Britta Fünfstück (Vorstandsvorsitzende/ CEO). Dr. Raymund Heinen. Michel Kuehn. 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

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The object of the declaration is in conformity with the relevant Union harmonization legislation:

- EN 420: 2003+ A1: 2009
- EN ISO 374-1: 2016 + A1: 2018
- EN ISO 374-5: 2016
- EN 421: 2010 (excluding clause 4.3)

The notified body SATRA Technology Europe Ltd, no. 2777 performed the EU type-examination (Module B) and issued the EU type-examination certificate (2777/10895-02/E01-01 (Peha-soft nitrile white) and 2777/10896-03/E01-01 (Peha-soft nitrile white)).

PAUL HARTMANN AG

ppa.

Dr. R. Heinen
Chief Process Officer

S. Fischer
Head of Regulatory Affairs

This document is valid until: 2023-07-18