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

Heidenheim, 2021-03-01

We herewith declare,

Object of the declaration: **Peha-taft LATEX (2078)**

which has been first placed on the market by PAUL HARTMANN AG, meets the applicable provisions, especially the essential requirements / essential health and safety requirements of the following EU-legislation:

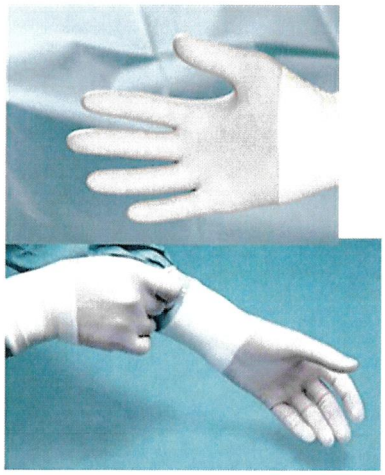
- **Council Directive 93/42/EEC for medical devices (MDD)**
- **Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment**

The required conformity assessment procedure according to MDD Annex II excluding Section (4) 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.

The conformity assessment procedure is under the supervision of the Notified Body:
TÜV SÜD Product Service GmbH, DE-80339 München, Ridlerstr. 65, Identification No. 0123.

Medical Device: Class IIa acc. to rule 7
(acc. to Annex IX of the directive)

UMDNS: 11-883



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Personal Protective Equipment Regulation:

The Object of the declaration is in conformity with the relevant harmonized standards used or with the technical specifications in relation to which conformity is declared:

- EN ISO 374-1:2016
  Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks
- EN ISO 374-5:2016
  Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks
- EN 420:2003+A1:2009
  Protective gloves - General requirements and test methods
- EN 421:2010 (Radioactive contamination only)
  Protective gloves against ionizing radiation and radioactive contamination

The notified body SATRA Technology Europe Ltd (2777) performed the EU type-examination (Module B) and issued the EU type-examination certificate 2777/11093-02/E01-01 (Peha-taft LATEX).

The PPE is subject to the conformity assessment procedure based on internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the notified boy SATRA Technology Europe Ltd (2777).

Paul Hartmann AG

ppa.

Martin Walther
Head of Business Division
Risk Prevention

ppa.

Stefan Fischer
Head of Regulatory Affairs

This document is valid until: 2023-08-16

ILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück (Vorsitzende des Vorstands/CEO), François Georgelin, Dr. Raymund Heinen, Michel Kuehn, Stefan Müller
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