

PAUL HARTMANN AG
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Germany

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www.hartmann.info



EU Declaration of Conformity

Heidenheim, 2023-06-27

We herewith declare under our sole responsibility that the class IIa medical devices listed below, first placed on the market by PAUL HARTMANN AG, Single Registration Number of Manufacturer DE-MF-000005861, satisfy the applicable provisions, in particular, the General Safety and Performance Requirements, of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5. April 2017 on medical devices.

The conformity assessment procedures according to Article 52 (6) and Annex IX have been performed and the Technical Documentation is kept available.

The conformity assessment procedures are under the supervision of the Notified Body TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123. Certificate No.: G10 011858 0065.

We herewith declare under our sole responsibility that the category III personal protective equipment listed below, first placed on the market by PAUL HARTMANN AG, satisfy the applicable provisions, in particular, the Essential Health and Safety Requirements (Annex II) of Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment.

The objects of the declaration also comply with the following:

- EN ISO 374-1:2016+ A1:2018 / Type B
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 EN 421:2010 (excluding clause 4.3)
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 2777/10568-03/E01-01.

GLN 404 9500 00000 0

Vorstand/Management Board: Britta Fünfstück
(Vorsitzende des Vorstands/CEO), François Georgelin,
Stefan Grote, 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
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Helps. Cares. Protects.

The Personal Protective Equipment 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 body SATRA Technology Europe Ltd (2777).

Device Group	T010102: Synthetic surgical gloves		
Intended Purpose	Single-use, non-active, non-implantable devices for wound and skin care		
Product Name	Product Group Number	Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)	Basic UDI-DI
Peha-isoprene latexfree	1992	7 (1)	40495001992LK

PAUL HARTMANN AG

ppa.

Martin Walther

Senior Vice President Risk Prevention

ppa.

Stefan Fischer

Senior Vice President Regulatory Affairs

Valid until: 2028-05-26

GLN 404 9500 00000 0

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