

Certification of Conformity

According to Module C2 of PPE Regulation EU 2016/425

Regulation (EU) 2016/425 of the European parliament and the council of 9 March 2016 on personal protective equipment

Product category: Personal Protective Equipment

Applicant: PEKA Medical GmbH
Konrad-Zuse-Straße 2
42551 Velbert
Germany

Manufacturer: PEKA Medical GmbH
Konrad-Zuse-Straße 2
42551 Velbert
Germany

Manufacturing location: PEKA Medical GmbH
Konrad-Zuse-Straße 2
42551 Velbert
Germany

The TÜV NORD CERT GmbH, notified body No. 0044, in accordance with Chapter V of Regulation (EU) 2016/425 of 9 March 2016 certifies the applicant that the manufacturer maintains a conformity monitoring procedure to ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type-examination certificate which is conform with the requirements stipulated in Annex VII (Module C2) of said regulation. The annex lists all supervised products and their pertinent certificate numbers

This notification is based on audit report No. 35307236. This notification can be withdrawn if the manufacturer no longer satisfies to the requirements of Annex VII. Results of periodical production quality reassessments are a part of this notification.

In accordance with Article 17 (3) of the Regulation (EU) 2016/425 the CE marking shall be followed by the identification number 0044 of the notified body TÜV NORD CERT GmbH.

The EU-Type Examination Certificates based on this notification are listed by the notified body.

Certificate Registration No. 44 786 212273
Order number: 8003037767

Date of issue: 2021-12-15
Valid to: 2022-12-14



TÜV NORD CERT GmbH
Certification Body Consumer Products

Essen, 2021-12-15

TÜV NORD CERT GmbH

Am TÜV 1

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ANNEXE

to Certificate Registration No. 44 786 212273

Annex 1, page 1 of 1

supervised products:

Filtering Half Mask FFP2 NR
318

EU type-examination - certificate numbers:

44 206 21151001

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TÜV NORD CERT GmbH
Certification Body Consumer Products

Essen, 2021-12-15