



EU DECLARATION OF CONFORMITY in accordance to the Regulation (EU) 2016/425 for personal protective equipment (PPE)

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Berner International GmbH, Werner-von-Siemens-Str. 19, 25337 Elmshorn, Germany hereby declares that the following personal protective equipment

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|------------------|--|
| Description: | Berner Protective sleeves of cleo® saphir - series |
| Specification: | Sterile and non-sterile |
| Colour: | Blue |
| Berner Item no.: | 6000, 6001, 6010, 6011, 6200, 6300 |

Complies with the requirements of the Regulation (EU) 2016/425 (Off. Journal of the EU L 81/31.3.2016) for personal protective equipment of category III and the harmonized standards (Off. Journal of the EU C 209/15.06.2018).

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| Relevant regulation: | Regulation (EU) 2016/425 for personal protective equipment |
| Applied harmonized standards: | EN ISO 13688:2022 and parts of EN 14605:2009 and EN 14126:2004 |
| Other relevant standards, applied or partly applied: | + DIN EN 14325:2018 + DIN EN 16523-1:2015 + ISO 16603:2004 + ISO 16604:2004 + ISO 22610:2018 + ISO 22612:2005 + DIN EN ISO 12947-2:2017 + DIN EN 863:1995 + DIN EN ISO 13934-1:2013 + DIN EN ISO 13935-2:2014 + EN ISO 7854:1997 + DIN EN ISO 9073-4:2021 |



The protective clothing is identical to the PPE, which is the object of the EU-type examination procedure with certificate no. CE 715808 (acc. to Module B), issued by the notified body 2797.

Notified Body 2797: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, NL

In addition, the PPE is subject to the conformity assessment procedure acc. to Module D, Annex VIII of Regulation (EU) 2016/425 under supervision of the notified body BSI (2797).

Signed for and in the name of
Berner International GmbH
Elmshorn, 16 March 2023

Dipl.-Ing. Sven Gragert
CE-Documentation representative