



## 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

Description: Bernern Protective sleeves of cleo® saphir - series

Specification: Sterile and non-sterile

Colour: Blue

Berner Item no.: 6000, 6001, 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).

Relevant regulation: Regulation (EU) 2016/425 for personal protective equipment

Applied harmonized standards: EN ISO 13688:2013 and parts of EN 14605:2005+A1:2009 and EN 14126:2003

Other relevant standards, applied or partly applied:

+ DIN EN 14325:2004	+ DIN EN 530:2010
+ DIN EN 16523-1:2015	+ DIN EN 863:1995
+ ISO 16603:2004	+ DIN EN ISO 13934-1 :1999
+ ISO 16604:2004	+ DIN EN ISO 13935-2:1999
+ ISO 22610:2006	+ EN ISO 7854:1997
+ ISO 22612:2005	+ DIN EN ISO 9073-4:1997



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 C2, Annex VII of Regulation (EU) 2016/425 under supervision of the notified body BSI (2797).

Signed for and in the name of  
Bernern International GmbH  
Elmshorn, 18 December 2020

Dipl.-Ing. Sven Gragert  
CE-Documentation representative