



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: Bernier Protective Gowns of **cleo® saphir - series**

Specification: Sterile and non-sterile

Colour: Blue

Berner Item no.: 6500, 6550, 6600, 6650, 6700, 6701,
6800, 6801, 6900, 6901, 100072, 100073

Complies with the requirements of the Regulation (EU) 2016/425 (Off. Journal of the EU L 81/31.03.2016) 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


CE 2797

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
Berner International GmbH
Elmshorn, 18 December 2020



Dipl.-Ing. Sven Gragert
CE-Documentation representative