



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:	Berner 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 13688:2022 and parts of EN 14605:2009 and EN 14126:2004
Other relevant standards, applied or partly applied:	DIN EN 14325:2018 DIN EN ISO 12947-2:2017 DIN EN 16523-1:2018 DIN EN 863:1995 ISO 16603:2004 DIN EN ISO 13934-1:2013 ISO 16604:2004 DIN EN ISO 13935-2:2014 ISO 22610:2018 EN ISO 7854:1997 ISO 22612:2005 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