



UKCA DECLARATION OF CONFORMITY

in accordance to the Regulation (EU) 2016/425 on personal protective equipment as amended to apply in GB

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) as brought into UK law and the designated standards for personal protective equipment of category III and harmonized standards (Off. Journal of the EU C 209/15.06.2018).

Relevant regulation: Regulation 2016/425 on personal protective equipment, as amended to apply in GB

Applied designated standards: EN ISO 13688:2022-04 and parts of EN 14605:2005+A1:2009 and EN 14126:2003

Other relevant standards, applied or partly applied:	DIN EN 14325:2018	DIN EN ISO 12947-2:2017-03
	DIN EN 16523-1:2018-12	DIN EN 863:1995-11
	ISO 16603:2004-04	DIN EN ISO 13934-1:2013-08
	ISO 16604:2004-04	DIN EN ISO 13935-2:2014-07
	ISO 22610:2018-09	EN ISO 7854:1997-04
	ISO 22612:2005-05	DIN EN ISO 9073-4:2021-05



The protective clothing is identical to the PPE, which is the object of the UKCA certification – PPE Regulation process, based on the original EU type examination procedure with the certificate UKCA 748723 (acc. to Module B), issued by the approved body 0086


Approved Body – BSI Assurance UK Ltd (0086), Kitemark Court, Davy Avenue Knowlhill, Milton Keynes, MK5 8PP, United Kingdom

The PPE is subject to the UKCA conformity assessment procedure acc. to Module D, Annex VIII Regulation 2016/425 on personal protective equipment, as amended to apply in GB under supervision of the approved body BSI (0086).

Signed for and in the name of

Berner International GmbH

Elmshorn, 28. June 2024


Dipl.-Ing. Sven Gragert
Authorised documentation representative