

Declaration of Conformity

Legal Manufacturer:

Guilin HBM Health Protections, Inc.
No.1-2, Shuijing East Road, Economic and
Technological Development Area, Guilin, China
SRN: CN-MF-000033439

Authorized Representative in the EU:

HBM Medical
Coliemore House, Coliemore Road,
Dalkey, Co. Dublin, Ireland.
SRN: IE-AR-000031279

Brand owner :

B.Braun Avitum AG
Schwarzenberger Weg 73-79
34212 Melsungen, Germany

Hereby declare in our own responsibility that the product :

Vasco® Surgical Poly
Vasco® Surgical Poly Underglove
Gloves, surgical, sterile
Basic UDI: 697178707SGPIU3

(article numbers see attachment I)

(1)

are in conformity with Annexes II and III of Regulation (EU) 2017/745 /
according to Article 52(7) of Regulation (EU) 2017/745

Notified Body :
SATRA Technology Europe Limited
Bracetown Business Park Clonee, D15 YN2P, Ireland
NUMBER: 2797 CERTIFICATE :
EU type-examination through Module D
Certificate No : CE 754434

(2)

are in conformity with Personal Protective Equipment Regulation (EU) 2016/425,
under Category III risk set out in Annex I,

meeting the provisions of EN ISO 21420:2020 + A1:2009, EN ISO 374-1:2016 + A1:2018, EN ISO
374-2:2019, EN ISO 374-4:2019, EN ISO 374- 5:2016 for EU Type Examination (Module D).

Notified body :

BSI Group The Netherlands B.V. Say Building,
John M. Keynesplein 9,
1066 EP Amsterdam, Netherlands
CE 2797

Certificate No: 747921

Date of first CE-marking:

2022-05-12

Valid until :

2027-05-11

Place, date

Pu lei/Quality Director Name and Position

ATTACHMENT I

Article Number	Product Name / Description
6031900	Vasco® Surgical Poly 5.5
6031918	Vasco® Surgical Poly 6
6031926	Vasco®Surgical Poly 6.5
6031934	Vasco® Surgical Poly 7
6031942	Vasco® Surgical Poly 7.5
6031959	Vasco® Surgical Poly 8
6031967	Vasco® Surgical Poly 8.5
6031975	Vasco® Surgical Poly 9
6041900	Vasco® Surgical Poly Underglove 5.5
6041918	Vasco® Surgical Poly Underglove 6
6041926	Vasco® Surgical Poly Underglove 6.5
6041934	Vasco® Surgical Poly Underglove 7
6041942	Vasco® Surgical Poly Underglove 7.5
6041959	Vasco® Surgical PolyUnderglove 8
6041967	Vasco® Surgical Poly Underglove 8.5
6041975	Vasco® Surgical PolyUnderglove 9