

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 Latex
Vasco® Surgical Latex Micro
Vasco® Surgical Latex Ortho
Gloves, surgical, sterile
Basic UDI: 697178707SGNRUF

(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
No: 2797
EU type-examination through Module D

Certificate No:
Issued Date:
Expiry Date:

(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: MDR 747921

Issue Date:

2022-05-12

Expiry Date :

2027-05-11

Place, date

Pu lei/Quality Director Name and Position

ATTACHMENT I

Article Number	Product Name / Description
6021900	Vasco® Surgical Latex 5.5
6021918	Vasco® Surgical Latex 6
6021926	Vasco® Surgical Latex 6.5
6021934	Vasco® Surgical Latex 7
6021942	Vasco® Surgical Latex 7.5
6021959	Vasco® Surgical Latex 8
6021967	Vasco® Surgical Latex 8.5
6021975	Vasco® Surgical Latex 9
6051900	Vasco® Surgical Latex Micro 5.5
6051918	Vasco® Surgical Latex Micro 6
6051926	Vasco® Surgical Latex Micro 6.5
6051934	Vasco® Surgical Latex Micro 7
6051942	Vasco® Surgical Latex Micro 7.5
6051959	Vasco® Surgical Latex Micro 8
6051967	Vasco® Surgical Latex Micro 8.5
6051975	Vasco® Surgical Latex Micro 9
6061900	Vasco® Surgical Latex Ortho 5.5
6061918	Vasco® Surgical Latex Ortho 6
6061926	Vasco® Surgical Latex Ortho 6.5
6061934	Vasco® Surgical Latex Ortho 7
6061942	Vasco® Surgical Latex Ortho 7.5
6061959	Vasco® Surgical Latex Ortho 8
6061967	Vasco® Surgical Latex Ortho 8.5
6061975	Vasco® Surgical Latex Ortho 9