B BRAUN

Konformitätserklärung

Declaration of Conformity

Wir | We

Digitally signed by Şarco Alexandru
Date: 2024.03.26 11:03:12 EET
Reason: MoldSign Signature
Location: Moldova

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Deutschland/Germany

erklären in eigener Verantwortung,
dass das/die Produkt/e

hereby declare in our own responsibility
that the product/s

Vasco® OP eco
Vasco® OP Free
Vasco® OP Grip
Vasco® OP Powdered
Vasco® OP Sensitive
Vasco® OP Underglove
Vasco® Surgical Chloroprene
Vasco® Surgical Micro
Vasco® Surgical Powder-free
Vasco® Surgical Powdered
Handschuh, chirurgisch, steril

(Artikelnummern siehe Anlage I)

Vasco® OP eco
Vasco® OP Free
Vasco® OP Grip
Vasco® OP Powdered
Vasco® OP Sensitive
Vasco® OP Underglove
Vasco® Surgical Chloroprene
Vasco® Surgical Micro
Vasco® Surgical Powder-free
Vasco® Surgical Powdered
Gloves, surgical, sterile

(article numbers see attachment I)

mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmen

is/are in compliance with the following directive

(1)
Richtlinie 93/42/EWG des Rates vom 14. Juni 1993
über Medizinprodukte,
geändert durch Richtlinie 2007/47/EG

(1)
Council Directive 93/42/EEC of 14 June 1993
concerning Medical Devices,
amended by Directive 2007/47/EG

Konformitätsbewertungsverfahren
nach Anhang II
ohne Abschnitt 4
der oben genannten Richtlinie

Conformity assessment procedure
according to annex II
without part 4
of the Directive named above

Klassifizierung
gemäß Anhang IX der oben genannten Richtlinie:
Klasse IIa

Classification
according to annex IX of the Directive named above:
Class IIa

Benannte Stelle
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Deutschland
Kennnummer 0123

Notified body
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Germany
Identification number 0123

Effective

sowie

(2)
in den einschlägigen Anforderungen der Verordnung (EU) 2016/425 des Europäischen Parlaments und des Rates vom 09.03.2016 über persönliche Schutzausrüstung

Klassifizierung
Kategorie III (hohes Risiko)

Benannte Stelle
SATRA Technology Europe Ltd
Bracetown Business Park
Clonee
Dublin
D15 YN2P
Ireland
Kennnummer 2777

Datum der ersten CE-Kennzeichnung
1996-10

Gültig bis
2024-03-17

Melsungen, 2019-03-18

i. V.

Thomas Möller
Vice President Quality Management
Systems & Quality Compliance

and

(2)
relevant requirements of the Regulation (EU) 2016/425 of the European Parliament and of the council of 09.03.2016 on personal protective equipment

Classification
Category III (high risks)

Notified body
SATRA Technology Europe Ltd
Bracetown Business Park
Clonee
Dublin
D15 YN2P
Ireland
Identification number 2777

Date of first CE-marking
1996-10

Valid until
2024-03-17

Melsungen, 2019-03-18

i. V.

Dr. Hans-Ulrich Gaudin
Head of Global Regulatory Affairs
OPM Germany

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product Name	Klasse / Class	Kategorie/ Category
6081308	Vasco® OP eco	IIa	III
6081316	Vasco® OP eco	IIa	III
6081324	Vasco® OP eco	IIa	III
6081332	Vasco® OP eco	IIa	III
6081340	Vasco® OP eco	IIa	III
6081359	Vasco® OP eco	IIa	III
6081367	Vasco® OP eco	IIa	III
6081375	Vasco® OP eco	IIa	III
9208291	Vasco® OP Free	IIa	III
9208305	Vasco® OP Free	IIa	III
9208313	Vasco® OP Free	IIa	III
9208321	Vasco® OP Free	IIa	III
9208330	Vasco® OP Free	IIa	III
9208348	Vasco® OP Free	IIa	III
9208356	Vasco® OP Free	IIa	III
9208364	Vasco® OP Free	IIa	III
6081409	Vasco® OP Grip	IIa	III
6081417	Vasco® OP Grip	IIa	III
6081425	Vasco® OP Grip	IIa	III
6081433	Vasco® OP Grip	IIa	III
6081441	Vasco® OP Grip	IIa	III
6081450	Vasco® OP Grip	IIa	III
6081468	Vasco® OP Grip	IIa	III
6081476	Vasco® OP Grip	IIa	III
6031510	Vasco® OP Powdered	IIa	III
6031525	Vasco® OP Powdered	IIa	III
6031532	Vasco® OP Powdered	IIa	III
6031546	Vasco® OP Powdered	IIa	III
6031553	Vasco® OP Powdered	IIa	III
6031564	Vasco® OP Powdered	IIa	III
6080990	Vasco® OP Sensitive	IIa	III
6081002	Vasco® OP Sensitive	IIa	III
6081010	Vasco® OP Sensitive	IIa	III
6081029	Vasco® OP Sensitive	IIa	III
6081037	Vasco® OP Sensitive	IIa	III
6081045	Vasco® OP Sensitive	IIa	III
6081053	Vasco® OP Sensitive	IIa	III
6081060	Vasco® OP Sensitive	IIa	III
6081199	Vasco® OP Underglove	IIa	III
6081200	Vasco® OP Underglove	IIa	III
6081218	Vasco® OP Underglove	IIa	III
6081226	Vasco® OP Underglove	IIa	III
6081234	Vasco® OP Underglove	IIa	III
6081242	Vasco® OP Underglove	IIa	III
6081259	Vasco® OP Underglove	IIa	III
6081267	Vasco® OP Underglove	IIa	III
6035700	Vasco® Surgical Chloroprene	IIa	III
6035712	Vasco® Surgical Chloroprene	IIa	III
6035724	Vasco® Surgical Chloroprene	IIa	III

6035736	Vasco® Surgical Chloroprene	IIa	III
6035748	Vasco® Surgical Chloroprene	IIa	III
6035751	Vasco® Surgical Chloroprene	IIa	III
6035763	Vasco® Surgical Chloroprene	IIa	III
6035775	Vasco® Surgical Chloroprene	IIa	III
6035800	Vasco® Surgical Micro	IIa	III
6035812	Vasco® Surgical Micro	IIa	III
6035824	Vasco® Surgical Micro	IIa	III
6035836	Vasco® Surgical Micro	IIa	III
6035848	Vasco® Surgical Micro	IIa	III
6035851	Vasco® Surgical Micro	IIa	III
6035863	Vasco® Surgical Micro	IIa	III
6035875	Vasco® Surgical Micro	IIa	III
6081100	Vasco® Surgical Powder-free	IIa	III
6081101	Vasco® Surgical Powder-free	IIa	III
6081111	Vasco® Surgical Powder-free	IIa	III
6081121	Vasco® Surgical Powder-free	IIa	III
6081131	Vasco® Surgical Powder-free	IIa	III
6081141	Vasco® Surgical Powder-free	IIa	III
6081151	Vasco® Surgical Powder-free	IIa	III
6081161	Vasco® Surgical Powder-free	IIa	III
6035500	Vasco® Surgical Powdered	IIa	III
6035518	Vasco® Surgical Powdered	IIa	III
6035526	Vasco® Surgical Powdered	IIa	III
6035534	Vasco® Surgical Powdered	IIa	III
6035542	Vasco® Surgical Powdered	IIa	III
6035559	Vasco® Surgical Powdered	IIa	III
6035567	Vasco® Surgical Powdered	IIa	III
6035575	Vasco® Surgical Powdered	IIa	III

Best Trados
birou de traduceri

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Traducere din limba engleză

B BRAUN

Declaraţie de Conformitate

Document nr. 084-001 (1)
Revizuire nr. 23
Data intrarii in vigoare: data ultimei semnături

Subscrisa
B. BRAUN MELSUNGEN AG
Carl-Braun-Strasse 1
34212 Melsungen
Germania

Declaram prin prezenta pe propria raspundere ca produsul/ele
Vasco® OP eco
Vasco® OP Free
Vasco® OP Grip
Vasco® OP Powdered
Vasco® OP Sensitive
Vasco® OP Underglove
Vasco® Surgical Chloroprene
Vasco® Surgical Micro
Vasco® Surgical Powder-free
Vasco® Surgical Powdered
Mănuşi chirurgicale, sterile
(articolele, a se vedea anexa I)
este/sunt în conformitate cu următoarea directivă
(1)
Directiva Consiliului 93/42/CEE din 14 iunie 1993 cu privire la Dispozitivele medicale
modificată de Directiva 2007/47/EG

Procedura de Evaluare a Conformităţii
conform anexei II
fără partea 4
la Directiva Consiliului de mai sus

Clasificare
conform anexei IX la Directiva Consiliului de mai sus
Clasa IIa

Organism notificat
TUV SUD Product Service GmbH
Ridlerstrasse 65
80339 Munchen
Germania
Numărul de identificare 0123
şi
(2)
cerinţele relevante din Regulamentul (UE) 2016/425 al Parlamentului European şi al Consiliului din 09.03.2016 privind echipamentul individual de protecţie
Clasificare
Categoria III (riscuri ridicate)

Organism notificat
SATRA Technology Europe Ltd
Bracetown Business Park
Clonee
Dublin
D15YN2P
Irlanda
Număr de identificare 2777

Data primului marcaj CE
10-1996

Valabil până la
17.03.2024

Melsungen, 18.03.2019
Thomas Moller
-semnătură indescifrabilă-
Vice-preşedinte Managementul Calităţii & Conformitate calitate

Melsungen, 18.03.2019
Dr. Hans-Ulrich Gaudin
Director Afaceri reglementate
OPM Germania
-semnătură indescifrabilă-

Subsemnata **VALERICA PĂTRU,** traducător autorizat de Ministerul Justiţiei pe limbile: FRANCEZĂ, ENGLEZĂ şi ITALIANĂ cu autorizaţia nr. 17602, certific exactitatea traducerii în limba ROMÂNĂ cu textul înscrisului original în limba ENGLEZĂ care mi-a fost prezentat.

Traducător autorizat,
Valerica Pătru
(17602)

Ministerul Justiției
VALERICA PĂTRU
Traducător interpret autorizat
Engleză, Franceză, Italiană
Autorizația nr. 17602