



qualityaustria
Succeed with Quality

CERTIFICAT

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH eliberează acest certificat **qualityaustria** următoarei societăți:

B | BRAUN

SHARING EXPERTISE

B. Braun Medical S.R.L.

Remetea Mare, Nr. 636, DN6 km 546+400 dreapta,
307350 Timiș, România
București, Șos. Andronache, Nr. 203,
022524 – Sector 2, România

Distribuția de produse medicale active,
pasive și implantabile.

Mentenanța, service-ul, repararea și revizia
aparaturii medicale pentru tratament perfuzabil,
dializă și nutriție parenterală.
Service și reparații pentru motoare chirurgicale
și unități de electrochirurgie Aesculap. Service
pentru instrumente chirurgicale Aesculap.

Valabilitatea acestui certificat **qualityaustria** se va
menține prin audituri anuale de supraveghere precum
și prin audituri de recertificare o dată la trei ani.

Acest certificat **qualityaustria** confirmă folosirea
și dezvoltarea ulterioară cu eficacitate a unui

SISTEM DE MANAGEMENT AL CALITATII
în conformitate cu cerințele

ISO 13485:2016

Dispozitive medicale - sisteme de management calitate -
Cerințe pentru scopuri de reglementare

Număr de înregistrare: 00200/5

Data primei eliberări: 28 iulie 2015

Valabil până la: 27 iulie 2021

Viena, 16 iulie 2018

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH,
AT-1010 Vienna, Zelinkagasse 10/3

Semnături eliminate pentru motive de securitate

Konrad Scheiber
Director

Ing. Andreas Aichinger, MSc
Responsabil de specialitate



Q qualityaustria



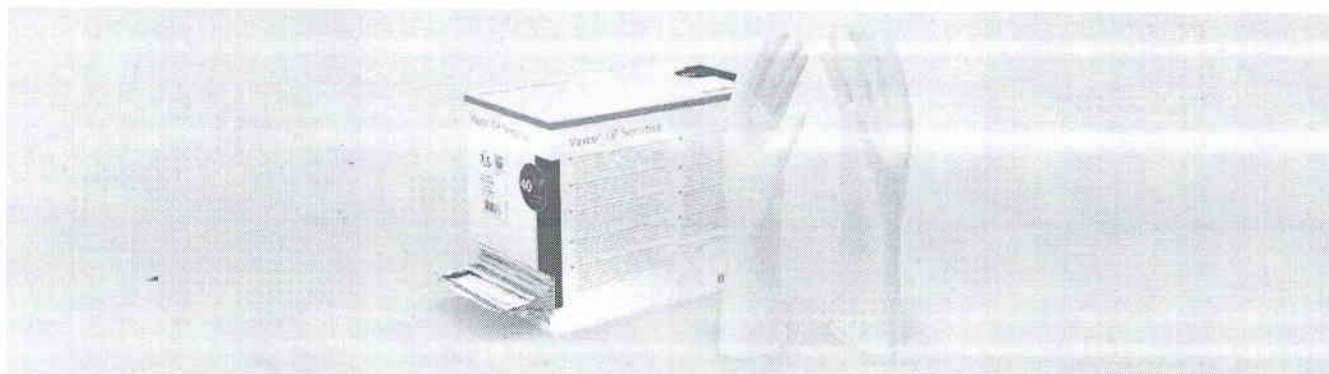
Valabilitatea acestui certificat este verificabilă în exclusivitate pe internet, la adresa
<http://www.qualityaustria.com/en/cert> EAC: 29

Doc. Nr. 10-04-001

12/01/2019-06:56:73-497d-
b7c6-e1a1a4a4a4a4

Vasco® OP Sensitive Sterile Surgical and Protective Gloves

DATA SHEET



STERILE R



EN 374:2003



EN 374:2003



AQL 0.65

**B. Braun Melsungen AG confirms that
Vasco® OP Sensitive gloves comply with the following standards and directives:**

EC CERTIFICATES AND APPLIED STANDARDS

Medical device class IIa CE 0123 (TÜV Süd, DE),
according to MDD 93/42/EEC
EN 455 1-4, ISO 10282, ISO 10993, ISO 11137,
ASTM D3577, ASTM D5712

Personal protective equipment category III CE 0321 (SATRA, UK)
according to 89/686/EEC
EN 420, EN 374 1-3, EN 16523, EN 388,
ASTM F1671, ASTM D6978

QUALITY CERTIFICATES

ISO 9001, ISO 13485

Certificates and complete list of applied standards are available on request.

B. Braun Melsungen AG

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



Vasco® OP Sensitive Sterile Surgical and Protective Gloves

TECHNICAL DATA



REF	SIZE	GLOVE DIMENSIONS (ACC. EN 455)		WALL THICKNESS	
		Width of palm	Total length	Single wall	
6080990	5.5	73 ± 3 mm	≥ 270 mm		
6081002	6	79 ± 3 mm	≥ 270 mm		
6081010	6.5	85 ± 3 mm	≥ 270 mm	finger	≥ 0.175 mm
6081029	7	91 ± 3 mm	≥ 280 mm	palm	≥ 0.195 mm
6081037	7.5	97 ± 3 mm	≥ 280 mm	cuff	≥ 0.16 mm
6081045	8	105 ± 3 mm	≥ 280 mm		
6081053	8.5	111 ± 3 mm	≥ 285 mm		
6081060	9	112 ± 3 mm	≥ 285 mm		

GLOVE DESIGN

Colour	natural white
Shape	fully anatomical shape with curved fingers
Cuff	rolled rim
Surface finish	micro rough, silicone treated
Inner glove surface	polymer coated, powder-free

GLOVE MATERIAL

Natural rubber latex	Protein content < 30 µg/g
Latex allergy risk	containing natural rubber latex which may cause allergic reactions including anaphylactic reactions

ACCELERATORS

Zn-dithiocarbamate

Free of thiurames, thioureas and thiazoles – including mercaptobenzothiazole MBT

PHYSICAL PROPERTIES

Force at break (median)	≥ 9 N during shelf life		
Elongation at break (median)	before ageing ≥ 830 %	after ageing	≥ 820 %
Tensile strength (median)	before ageing ≥ 30 MPa	after ageing	≥ 26 MPa
Water-tightness	AQL 0.65		

STERILIZATION

Gamma irradiation

LOGISTIC INFORMATION

Peel pouch	sterile film peel packs with 1 pair of gloves left/right with folded cuffs in paper cover		
Packaging dimensions	peel pouch	270 x 150 mm	
	dispenser box	270 x 150 x 205 mm (L x W x H)	
Packaging levels	40 pairs/box	10 boxes/carton (400 pairs)	
Shelf life	3 years		
Storage conditions	store at room temperature, protect from dust, humidity, sun light and ozone		



Vasco® OP Sensitive Sterile Surgical and Protective Gloves

BARRIER PROPERTIES – CHEMICALS



Tested by SATRA, UK and ProQuares, NL in accordance with

EN 374-3: Protective gloves against chemicals and micro-organisms – Determination of resistance to permeation by chemicals.

CHEMICAL	CAS REGISTRY NO.	PERMEATION PERFORMANCE LEVEL	BREAKTHROUGH TIME
Acetic acid 10 %	64-19-7	level 6	> 480 min
Acetone	67-64-1	not recommended	immediate
Acetonitrile	75-05-8	splash guard	1 – 10 min
Acrylamide 40 %	79-06-1	level 6	> 480 min
Ammonium hydroxide 25 %	1336-21-6	splash guard	1 – 10 min
Chlorhexidine digluconate 0.5 %	18472-51-0	level 6	> 480 min
Chlorhexidine 4 %	55-56-1	level 6	> 480 min
Chloroform	67-66-3	not recommended	immediate
Cyclohexanol	108-93-0	level 2	> 30 min
Dichloromethane	75-09-2	not recommended	immediate
Diesel fuel (100 %)		splash guard	1 – 10 min
Diethylamine	109-89-7	not recommended	immediate
Diethyl ether	60-29-7	not recommended	immediate
Dimethyl sulfoxide DMSO	67-68-5	level 2	> 30 min
Ethanol 20 %	64-17-5	splash guard	1 – 10 min
Ethanol 80 %	64-17-5	splash guard	1 – 10 min
Ethidium bromide 1 %	1239-45-8	level 6	> 480 min
Ethyl acetate	141-78-6	splash guard	1 – 10 min
Formaldehyde 37 % (in Methanol 10 %)	50-00-0	level 6	> 480 min
Glutaraldehyde 5 %	111-30-8	level 6	> 480 min
Heptane-n	142-82-5	not recommended	immediate
Hexane-n	110-54-3	not recommended	immediate
Hydrochloric acid 10 %	7647-01-0	level 6	> 480 min
Hydrochloric acid 36 %	7647-01-0	level 1	> 10 min
Iodine 1 % (in Alcohol 70 %)	7553-56-2	level 6	> 480 min
Isopropyl alcohol	67-63-0	splash guard	1 – 10 min
Linseed oil		level 6	> 480 min
Methanol	67-56-1	splash guard	1 – 10 min
Methyl methacrylate	80-62-6	splash guard	1 – 10 min
Nitric acid 10 %	7697-37-2	level 6	> 480 min
Nitric acid 50 %	7697-37-2	level 3	> 60 min
Povidone-iodine 10 %	25655-41-8	level 6	> 480 min
Sodium hydroxide 30 %	1310-73-2	level 6	> 480 min
Sodium hydroxide 40 %	1310-73-2	level 6	> 480 min
Sodium hypochlorite 10 %	7681-52-9	level 6	> 480 min
Sulfuric acid 30 %	7664-93-9	level 6	> 480 min
Sulfuric acid 96 %	7664-93-9	level 1	> 10 min
Toluene	108-88-3	not recommended	immediate
Trichloroethane	71-55-6	not recommended	immediate
Xylene	1330-20-7	splash guard	1 – 10 min



Vasco® OP Sensitive Sterile Surgical and Protective Gloves

BARRIER PROPERTIES – CYTOSTATIC DRUGS



Tested by ARDL, USA and ProQuares, NL in accordance with

EN 374-3: Protective gloves against chemicals and micro-organisms – Determination of resistance to permeation by chemicals. Minimum detection rate 1 µg/cm²/min ①

ASTM F 739: Standard Test Method for Resistance of Protective Clothing Materials to Permeation by Liquids or Gases under Conditions of Continuous Contact. Minimum detection rate 0,1 µg/cm²/min ②

ASTM D 6978: Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs. Minimum detection rate 0,01 µg/cm²/min ③

CLASSIFICATION

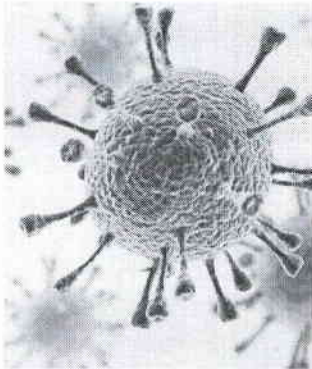
- Not suitable
- Suitable if changed before permeation breakthrough
- Suitable for prolonged use

CHEMOTHERAPY DRUG	mg/ml	CAS registry no.	MIN BREAKTHROUGH DETECTION TIME
Bleomycin sulphate	15	9041-93-4	■ > 240 min ③
Carboplatin	10	41575-94-4	■ > 240 min ③
Carmustine (BiCNU)	3.3	154-93-8	■ 15 min ②
Cisplatin	1.0	15663-27-1	■ > 240 min ②
Cyclophosphamide (Cytoxan)	20.0	6055-19-2	■ > 240 min ②
Cytarabine HCl	100	147-94-4	■ > 240 min ③
Dacarbazine (DTIC)	10.0	4342-03-4	■ > 240 min ②
Daunorubicin HCl	5	20830-81-3	■ > 240 min ③
Doxorubicin HCl	2.0	25316-40-9	■ > 240 min ②
Docetaxel	10	114977-28-5	■ > 240 min ③
Epirubicin	2.0	56420-45-2	■ > 240 min ③
Etoposide	20.0	33419-42-0	■ 15 min ②
5-Fluorouracil	50.0	51-21-8	■ 35 min ②
Gemcitabine	38	95058-81-4	■ > 240 min ③
Idarubicin	1	58957-92-9	■ > 240 min ③
Irinotecan	20	100286-90-6	■ > 240 min ③
Ifosfamide	50	3778-73-2	■ 120 min ③
Melphalan (Alkeran)	5.0	148-82-3	■ > 480 min ①
Methotrexate (Amethopterin Hydrate)	25.0	59-05-2	■ > 240 min ②
Mitomycin C	0.5	50-07-7	■ > 480 min ①
Mitoxantrone	2.0	65271-80-9	■ > 240 min ②
Oxaliplatin	5	63121-00-6	■ > 240 min ③
Paclitaxel (Taxol)	6.0	33069-62-4	■ > 240 min ②
Thio-Tepa	10.0	52-24-4	■ 40 min ②
Topotecan	1	123948-87-8	■ > 240 min ③
Vinblastin	1	865-21-4	■ > 240 min ③
Vinorelbine	0.1	71486-22-1	■ > 240 min ③
Vincristine	1.0	57-22-7	■ > 240 min ③



Vasco® OP Sensitive Sterile Surgical and Protective Gloves

BARRIER PROPERTIES – VIRAL PENETRATION



Tested by NELSON, USA in accordance with

ASTM F 1671: Standard Test Method for Resistance of Materials used in Protective Clothing to Penetration by Blood Borne Pathogens using Phi-X 174 Bacteriophage Penetration as a Test System.

Specimens that exhibit no detectable (< 1 PFU/mL) Phi-X174 in the assay titer pass the test.

TEST RESULT	ASSESSMENT		VALUE
Pass	No plaques	No virus penetration	< 1 PFU/mL (PFU: Plaque-forming unit)

NOTE

All tests are conducted under laboratory conditions. The product properties are directly dependant upon the conditions of use. The gloves should be checked in advance for any holes or tears. Damaged or swelling gloves must be replaced immediately. In general, it is recommended to change gloves after 1-2 hours of working. In special cases, double gloving (colored underglove as indicator glove and white overglove) may be appropriate.

Tests and certificates can only be regarded as general information and do not reflect all actual working conditions. Glove selection shall be based on a risk assessment procedure. Hand hygiene by rubbing or washing is basic for hand decontamination before and after glove use.





Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 18 04 12974 457

Manufacturer:

B. Braun Melsungen AG

Carl-Braun-Str. 1
34212 Melsungen
GERMANY



Product Category(ies):

Sterile non-active medical devices for

- Infusion, transfusion, nutrition and transfer devices
- Anaesthesia incl. accessories
- Urology, suction and drainage incl. accessories
- Catheterization and ventilation
- Oxygen therapy incl. accessories
- Incontinence
- Examination Gloves
- Wound care

**as well as related configured customized sets
Irrigation systems for diagnostic**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.:

713128920

Valid from:

2018-05-02

Valid until:

2023-05-01



Date, 2018-04-27

S. Preiß

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 2



Stefan Preiß



Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 18 04 12974 457

Facility(ies):

B. Braun Medical Kft Production Division
Déli-Külhatár út 2-4, 3200 Gyöngyös, HUNGARY

B. Braun Medical SAS
13 rue Croix Comtesse, 28402 Nogent-le-Rotrou, FRANCE

B. Braun Melsungen AG
Carl-Braun-Str. 1, 34212 Melsungen, GERMANY

B. Braun Medical Industries Sdn. Bhd.
Bayan Lepas Free Industrial Zone, 11900 Penang, MALAYSIA

B. BRAUN Vietnam Co., Ltd.
Thanh Oai Industrial Complex, Thanh Oai District, 156800 Hanoi,
VIETNAM

B. Braun Medical AG
Hauptstraße 39, 6182 Escholzmat, SWITZERLAND

ALMO-Erzeugnisse Erwin Busch GmbH
Große Allee 84, 34454 Bad Arolsen, GERMANY

B. BRAUN Vietnam Co., Ltd.
170 La Thanh Road, Dong Da District, 63000 Hanoi, VIETNAM

B. Braun Medical Inc.
901 Marcon Boulevard, Allentown PA 18109-9341, USA

