

DECLARATION OF CONFORMITY

MEDICAL DEVICE REGULATION (EU) 2017/745

PERSONAL PROTECTIVE EQUIPMENT REGULATION (EU) 2016/425

Legal Manufacturer

Semperit Investments Asia Pte. Ltd.
8 Jurong Town Hall Road,
#29-03 to 06 The JTC Summit,
Singapore 609434, Singapore
sempermed@semperitgroup.com

Authorized representative in the EU

Semperit Technische Produkte GmbH
Modecenterstraße 22, 1030 Vienna, Austria

Brand owner

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

This certificate is valid for the following product:

Non-sterile examination and protective glove for single use

Classification: Class I according to MD Regulation (EU) 2017/745
Category III according to PPE Regulation (EU) 2016/425

Basic UDI-DI: 9001570N*F-030VB-N-3RB

Vasco Nitril Soft blue

Sizes	X-Small	Small	Medium	Large	X-Large
Article codes	3000011181	3000011182	3000011183	3000011184	3000011185
Article codes	9201107	9201115	9201123	9201131	9201149

We hereby declare under sole responsibility that the CE marked product described above conforms to the requirements of the regulation for medical devices (EU) 2017/745.

Declaration based on Annex IV. Classification according rule 5, appendix VIII.

Applied standards: EN 455-1:2000, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, ISO 13485:2016, EN ISO 14971:2013, ISO 15223-1:2016, ISO 10993-1:2018, ISO 2859-1:1999 AMD 1:2011, IEC 62366-1:2015 / COR 1:2016

We hereby declare under sole responsibility that the CE marked product described above conforms with the applicable provisions of Regulation (EU) 2016/425 on personal protective equipment and is identical to the personal protective equipment which is subject to EU Type Examination Certificate No. 2777/11466-01/E01-01 issued by:

SATRA Technology Europe Ltd, ID No. 2777


Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

The products are subject to the procedure set out in Annex VII (Module C2) of Regulation (EU) 2016/425 under the supervision of

SATRA Technology Europe Ltd, ID No. 2777

Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Applied standards: EN 420:2003+A1:2009, ISO 374-1:2016/AMD 1:2018, EN 374-2:2014, EN 16523-1:2015+A1:2018, EN 374-4:2013, EN ISO 374-5:2016, ISO 2859-1:1999 AMD 1:2011


Andreas Wöss
Director


Released by: Christian Rohrbach

This signed document is valid for all translations attached.

Issued : Singapore, 2020-02-03

Expires: 2022-02-02

Effective

Vasco® Nitril Soft blue

NON STERILE EXAMINATION AND PROTECTIVE GLOVES | DATA SHEET



**B. Braun Melsungen AG confirms that
Vasco® Nitril Soft blue gloves comply with the following standards and directives:**

EC CERTIFICATES AND APPLIED STANDARDS

Medical Device Class I according to Medical Device Directive (MDD) 93/42/EEC

EN 455 1-4, ISO 11193-1, ASTM D6319

Personal Protective Equipment Category III according to Personal Protective Equipment Regulation (PPER) EU 2016/425

EN 420, EN 374, EN 16523, ISO 16604, ASTM F1671, ASTM D6978

QUALITY CERTIFICATES

ISO 9001, ISO 13485

PERSONAL PROTECTIVE EQUIPMENT

Information and Declaration of Conformity according to PPER (EU) 2016/425:



www.bbraun.com/gloves-declarations-of-conformity

B. Braun Melsungen AG

A handwritten signature in blue ink, appearing to read 'H. Gaudin', written over a horizontal line.

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

Vasco® Nitril Soft blue

NON STERILE EXAMINATION AND PROTECTIVE GLOVES | REGULATORY INFORMATION

MEDICAL DEVICE INFORMATION

MDD 93/42/EEC (CLASS I), EN 455



FOOD COMPLIANCE



Conformity for food contact according to 1935/2004/EEC

PERSONAL PROTECTIVE EQUIPMENT INFORMATION

Tested in accordance with:

ISO 374-1/Type B



KPT



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PPE Regulation (EU) 2016/425 (Cat. III); EN 420:2003+A1:2009

Code letter	Test chemical	EN 374-1:2016 Permeation level	EN 374-4:2013 Mean degradation
K	Sodium hydroxide 40 %	Level 6	-9,5 %
P	Hydrogen peroxide 30 %	Level 6	44,0 %
T	Formaldehyde 37 %	Level 4	51,0 %

Tested acc. to EN 16523-1:2015

Performance levels acc. EN 374-1:2016 +A1:2018	1	2	3	4	5	6
Measured breakthrough times (mins)	> 10	> 30	> 60	> 120	> 240	> 480

Degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemical. NOTE: Where the test specimens gave an increased puncture force after chemical exposure, the result is reported as a negative degradation.

AQL 1.0

Resistance to bacteria and fungi	pass
Resistance to virus	pass

ISO 374-5:2016



VIRUS

This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals. The chemical and penetration resistance has been assessed under laboratory conditions from samples taken from the palm only and relates only to the chemical tested. It can be different if the chemical is used in a mixture. It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on temperature, abrasion and degradation. When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves. Before usage, inspect the gloves for any defect or imperfections.

Vasco® Nitril Soft blue

NON STERILE EXAMINATION AND PROTECTIVE GLOVES | TECHNICAL DATA



SIZE	REF 200/180* pcs.	GLOVE DIMENSIONS (EN 455)	
		Width of palm	Total length
XS	9201107	≤ 80 mm	≥ 240 mm
S	9201115	80 ± 10 mm	
M	9201123	95 ± 10 mm	
L	9201131	110 ± 10 mm	
XL*	9201149	≥ 110 mm	

PHYSICAL PROPERTIES

		Min. specification	Typical value
Wall thickness	Finger	0.05 mm	0.09 mm
	Palm	0.05 mm	0.06 mm
	Cuff	0.04 mm	0.05 mm
Force at break	During shelf life	6 N	7 N after ageing
Elongation at break	Before ageing	500 %	600 %
	After ageing	400 %	540 %
Tensile strength	Before ageing	14 MPa	33 MPa
	After ageing	14 MPa	34 MPa

GLOVE DESIGN

Colour	violet blue
Shape	straight fingers, ambidextrous fitting
Cuff	rolled rim, regular cuff
Surface finish	fingertip textured
Inner glove surface	online chlorinated, powder-free

GLOVE MATERIAL

Nitrile butadiene rubber (NBR)	
Latex allergy risk	free of latex proteins

ACCELERATORS

Zn-dithiocarbamate, Zn-mercaptobenzoethiazolate

Free of thiurames

LOGISTIC INFORMATION

Dispenser pack	200 / 180 pcs.	245 x 125 x 74 mm (L x W x H)
Transportation carton	10 dispenser packs	380 x 258 x 255 mm (L x W x H)
Shelf life	3 years	
Storage conditions	store at room temperature, protect from dust, humidity, sun light and ozone	

Vasco® Nitril Soft blue

NON STERILE EXAMINATION AND PROTECTIVE GLOVES | BARRIER PROPERTIES – CHEMICALS



Tested by SATRA, UK in accordance with

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

EN 16523-1: Determination of material resistance to permeation by chemicals.

CHEMICAL	CAS REGISTRY NO.	PERMEATION PERFORMANCE LEVEL	BREAKTHROUGH TIME
Acetic acid 10 %	64-19-7	level 3	> 60 min
Acetone	67-64-1	not recommended	immediate
Acetonitrile	75-05-8	not recommended	immediate
Acrylamide 40 %	79-06-1	level 6	> 480 min
Ammonium hydroxide 25 %	1336-21-6	not recommended	1 – 10 min
Chloroform	67-66-3	not recommended	immediate
Dichloromethane	75-09-2	not recommended	immediate
Diethylamine	109-89-7	not recommended	immediate
Diethyl ether	60-29-7	not recommended	immediate
Dimethylsulfoxide	67-68-5	not recommended	immediate
Ethanol 20 %	64-17-5	level 1	> 10 min
Ethidium bromide 1 %	1239-45-8	level 6	> 480 min
Formaldehyde 37 %	50-00-0	level 4	> 120 min
Gasoline	8032-32-4	not recommended	immediate
Glutaraldehyde 5 %	111-30-8	level 6	> 480 min
Hydrochloric acid 10 %	7647-01-0	level 6	> 480 min
Hydrogen peroxide 30 %	7722-84-1	level 6	> 480 min
Nitric acid 10 %	7697-37-2	level 6	> 480 min
Phenol 10 %	108-95-2	not recommended	immediate
Sodium hydroxide 40 %	1310-73-2	level 6	> 480 min
Sulfuric acid 96 %	7664-93-9	not recommended	1 – 10 min
Toluene	108-88-3	not recommended	immediate
Trichloroethane	71-55-6	not recommended	immediate
Xylene	95-47-6	not recommended	immediate

Vasco® Nitril Soft blue

NON STERILE EXAMINATION AND PROTECTIVE GLOVES | BARRIER PROPERTIES – CYTOSTATIC DRUGS



CLASSIFICATION

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

Tested by ARDL, USA in accordance with

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







CHEMOTHERAPY DRUG	MG/ML	CAS REGISTRY NO.	MIN BREAKTHROUGH DETECTION TIME
Carmustine	3.3	154-93-8	■ 15 min
Cisplatin	1.0	15663-27-1	■ > 240 min
Cyclophosphamide	20.0	6055-19-2	■ > 240 min
Cytarabine	100.0	147-94-4	■ > 240 min
Dacarbazine	10.0	4342-03-4	■ > 240 min
Doxorubicin hydrochloride	2.0	25316-40-9	■ > 240 min
Etoposide	20.0	33419-42-0	■ > 240 min
Fluorouracil	50.0	51-21-8	■ > 240 min
Ifosfamid	50.0	3778-73-2	■ > 240 min
Methotrexate	25.0	59-05-2	■ > 240 min
Mitomycin C	0.5	50-07-7	■ > 240 min
Mitoxantrone	2.0	70476-82-3	■ > 240 min
Paclitaxel (Taxol)	6.0	33069-62-4	■ > 240 min
Thio-Tepa	10.0	52-24-4	■ 14 min
Vincristine sulfate	1.0	2068-78-2	■ > 240 min

en INSTRUCTIONS FOR USE Glove for single use compliant with PPE regulation (EU) 2016/425, EN 420 and EN ISO 374.

Instructions for use are to be used in combination with the specific product related information on each product packaging. The gloves are sold as a bundled unit within the shipping carton. In case this bundled unit is dismantled and products are sold separately, the distributor must ensure that the instructions for use are accompanied with each separate unit.

The gloves are classified as Personal Protective Equipment (PPE) Category III according to PPE Regulation (EU) 2016/425 and have been shown to comply with this regulation through the applicable harmonised European standards. These gloves are designed to provide protection against specific chemicals tested, micro-organisms and particulate radioactive contamination (if applicable). The gloves meet the EN/ISO standards shown on each specific packaging. This PPE is single-use only and to be disposed after contamination.

EXPLANATION OF STANDARDS AND PICTOGRAMS

EN ISO 374-1	Permeation levels are based on breakthrough times (tested acc. EN 16523-1:2015) as follows:						
Type A / B / C	Permeation level acc. EN ISO 374-1:2016 +A1:2018	1	2	3	4	5	6
	Minimum breakthrough time in minutes	10	30	60	120	240	480
	Type A = chemical breakthrough time > 30 minutes against at least 6 chemicals from the list Type B = chemical breakthrough time > 30 minutes against at least 3 chemicals from the list Type C = chemical breakthrough time > 10 minutes against at least 1 chemical from the list TEST CHEMICALS: A = Methanol / B = Acetone / C = Acetonitrile / D = Dichloromethane / E = Carbon disulphide / F = Toluene / G = Diethylamine / H = Tetrahydrofuran / I = Ethyl acetate / J = n-Heptane / K = Sodium hydroxide 40% / L = Sulphuric acid 96% / M = Nitric acid 65% / N = Acetic acid 99% / O = Ammonium hydroxide 25% / P = Hydrogen peroxide 30% / S = Hydrofluoric acid 40% / T = Formaldehyde 37%						
ABCDEFGHIJKLMNOST							
EN 374-4:2013	The degradation (in %) indicates the change in puncture resistance of the gloves after exposure to the respective challenge chemical.						
This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals. The chemical resistance has been assessed under laboratory conditions from samples taken from the palm only and relates only to the chemical tested. It can be different if the chemical is used in a mixture. It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on temperature, abrasion and degradation. When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves. Before usage, inspect the gloves for any defect or imperfections.							
EN ISO 374-5: 2016	Tested for resistance to penetration according to EN 374-2:2014	EN 421:2010	Protection against particulate radioactive contamination.				
	Tested for resistance to penetration by blood-borne pathogens according to EN ISO 374-5 / ASTM F1671 (virus resistance). Resistance to bacteria and fungi – pass Resistance to virus – pass The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.		These gloves do not protect against mechanical risks.				
Virus			PPE is for single-use only and must not be reused.				
 XXXX	XXXX = Identification number of notified Body responsible for the EU type examination and supervising ongoing conformity.		Before usage read instructions for use carefully.				
		EN 420:2003+A1:2009					

PRECAUTIONS FOR USE

Always check the gloves for possible mechanical damage, e.g. holes or tears, before use. Do not use damaged gloves. Glove length is appropriate to the end use where the risk to the wrist area is minimal.

TEMPERATURE LIMIT



STORAGE INSTRUCTIONS

Keep storage area cool, dry and dust free, avoid ventilation and storage close to photocopy equipment. Protect gloves against ultraviolet light sources, sunlight, oxidizing agents and ozone. Store in original packaging according to the temperature limit, provided on the packaging.

INGREDIENTS / HAZARDOUS INGREDIENTS

Some gloves might contain ingredients which are known to possibly cause skin irritations or allergic reactions with sensitised persons. Check warning information on specific packaging carefully. Formulation available on request.

DISPOSAL INSTRUCTIONS

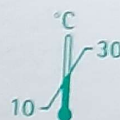
Dispose of the gloves in accordance with the valid regulations for this material. Gloves contaminated with chemical substances must be disposed of in accordance with the regulations for the relevant chemicals.

Vasco® Nitril Soft blue

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MDD 93/42/EEC (Class I), EN 455



REF 9201131

PZN 12907774

XS/5-6 S/6-7 M/7-8 **L/8-9** XL/9-10

Art. no: 9201131

Manufacturing site:
Latexx Partners Berhad,
Jalan Perusahaan 3, 34600
Kamunting, Perak, Malaysia

Made in: MALAYSIA



B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen
Germany

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...as de exam e luvas de protecção
nitrilo para uso único. Ambidextras.
...primento conforme EN 455 -
...adequadas para a utilização prevista, com
um risco mínimo para o pulso. Isento de
pó. Isentas de látex natural. Contém
ditiocarbamato e mercaptobenzotiazolato
de zinco. Não utilizar em caso de
hipersensibilidade a estes componentes.

Nitrylowe rękawice medyczne
rękawice ochronne do jednorazowego
użytku. Obureczne. Niepudrate. Fără latex

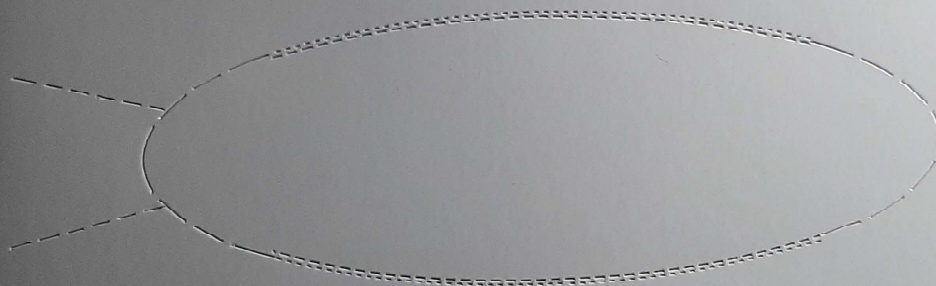
Mănuși de examinare și mănuși de
protecție din nitril de unică folosință.
Ambidextre. Lungime cf. EN 455 -
adevătată pentru domeniul de utilizare,
cu risc minim pentru articulația
radiocarpiană. Nepudrate. Fără latex

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Vasco® Nitril Soft blue



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Vasco® Nitril Soft blue

es Guantes de exploración de nitrilo y guantes de protección de un solo uso. Ambidestro. Longitud conforme a EN 455 - apropiado para el uso previsto con mínimo riesgo en la muñeca. Sin polvo. No contienen látex natural. Contienen ditiocarbamato y mercaptobenzotiazolato de zinc, no utilizar en caso de hipersensibilidad. Encontrará detalles sobre los datos de permeabilidad en www.bbraun.com. Proteger contra el ozono. Comprobar si hay daños antes del uso; no usar guantes dañados. No estéril.

et Ühekordselt kasutatavad nitrilkummist protseduurikindad ja kaitsekindad. Sobivad mõlemale käele. Pikkus standardi EN 455 järgi - sobivad sihipäraseks kasutamiseks randmele minimaalse ohuga. Puudrivabad. Ei sisalda looduslikku lateksit. Sisaldab ditiokarbamaati ja tsinkmerkaptobensotiasolaati, mitte kasutada ülitundlikkuse korral. Täpsed läbivuskindlusandmed on aadressil www.bbraun.com. Kaitsta osoonist eest. Enne kasutamist kontrollige, kas on kindad on terved; ärge kasutage kahjustatud kindaid. Mittesteriilsed.

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...thiazolaat, niet
...vergevoeligheid hiervoor.

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rtu EN 455 -
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no Undersøkelseshansker og beskyttelseshansker til engangsbruk av nitril. Ambidekstrøs. Lengde i henhold til EN 455 - passende for tiltenkt bruk med minimal risiko ved håndledet. Pulverfri. Fri for naturlateks. Innholder ditiokarbamat og sinkmerkaptobenzotiazolat. Må ikke brukes ved overfølsomhet.

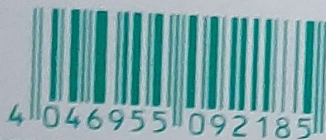
ru Нитриловые перчатки медычне
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pt Luvas de exame e luvas de em nitrilo para uso único. Am Comprimento conforme EN 455 adequadas para a utilização pr um risco mínimo para o pulso. pó. Isentas de látex natural. C ditiocarbamato e mercaptoben de zinco. Não utilizar em caso hipersensibilidade a estes com

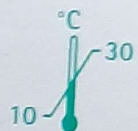
ro Mănuși de examinare și m protecție din nitril de unică fol Ambidextre. Lungime cf. EN 455 adecvată pentru domeniul de ut cu risc minim pentru articulația radiocarpiară. Nepudrate. Fără

Vasco® Nitril Soft blue

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MDD 93/42/EEC (Class I), EN 455



REF 9201131

PZN 12907774

XS/5-6 S/6-7 M/7-8 **L/8-9** XL/9-10



B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen
Germany

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...雙手。長度 i henhold til
EN 455 - passende for tiltenkt bruk med
minimal risiko ved håndledet. Pulverfri.
Fri for naturlateks. Inneholder
ditiokarbamat og
merkaptobenzotiazolat. Må ikke
brukes ved overfølsomhet.

☐ Nitrylowe rękawice medyczne
i rękawice ochronne do jednorazowego
użytku. Ochronne. Ochronne.

...de exame e luvas de protecção
nitrilo para uso único. Ambidextras.
Comprimento conforme EN 455 -
adequadas para a utilização prevista, com
um risco mínimo para o pulso. Isento de
pó. Isentas de látex natural. Contêm
ditiocarbamat e mercaptobenzotiazolato
de zinco. Não utilizar em caso de
hipersensibilidade a estes componentes.

☐ Mănuși de examinare și mănuși de
protecție din nitril de unică folosință.
Ambidextre. Lungime cf. EN 455 -
adevărată pentru domeniul de utilizare,
cu risc minim pentru articulația
radiocarpiană. Neputem...

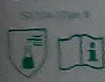
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PPE Regulation (EU) 2016/425 (Cat. III); EN 420:2003+A1:2009

Tested in accordance with:



Test chemical	EN 374-1:2016+A1:2018 Permeation Level	EN 374-4:2013 Mean degradation
A Sodium hydroxide 40%	6	9.5 %
P Hydrogen peroxide 30%	6	84.0 %
T Formaldehyde 37%	4	51.0 %

tested acc. to EN 18523-1:2015

ISO 374-5:2016

AOL < 1.5



VIRUS

Protection against bacteria and fungi - pass
Protection against virus - pass
Tested for resistance to penetration acc.
to EN 374-2:2014 / acc. to ASTM F1671.

This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals. The chemical and penetration resistance has been assessed under laboratory conditions from samples taken from the palm only and relates only to the chemical tested. It can be different if the chemical is used in a mixture. It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on temperature, abrasion and degradation. When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves. Before usage, inspect the gloves for any defect or imperfections.

Performance levels acc. to EN 374-1:2016+A1:2018
Puncture resistance (puncture force in mN)

1	2	3	4	5	6
>10	>30	>80	>120	>240	>480

Degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemical. NOTE: Where the test specimens gave an increased puncture force after chemical exposure, the result is reported as a negative degradation.



Declaration of Conformity with
Personal Protective Equipment Regulation
(EU) 2016/425: www.bbabraun.com/gloves-declarations-of-conformity



CE 2777

Notified Body responsible for
certification and ongoing conformity:
SATRA Technology Europe Ltd,
Bracegown Business Park,
Clonect, Dublin, D15 YN2P,
Ireland



www.bbabraun.com