bsi.

By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 01966**

Issued To: **Mölnlycke Health Care AB**
Box 13080
Gamlestadsvägen 3C
SE-402 52 Göteborg
Sweden

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **1998-06-29** Date: **2018-05-30** Expiry Date: **2023-06-28**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

"TEHNOMEDICA" S.R.L. 1002600063

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Certificate No: CE 01966

Certificate Scope:

Those aspects of manufacture related to securing and maintaining sterility of absorbent tracheostomy dressing, sterile scar management dressing and transparent adhesive IV film dressing.

Those aspects of manufacture related to securing and maintaining sterility of negative pressure wound therapy (NPWT) accessories, surgical and equipment drapes and surgical gowns.

Those aspects of manufacturing relating to securing and maintaining sterility in the assembly of procedure packs in accordance with article 12 of the MDD.

First Issued: **1998-06-29** Date: **2018-05-30** Expiry Date: **2023-06-28**

...making excellence a habit.™

We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden being the assembler of the following declare that the procedure packs listed in the attached schedule are in conformity with the provisions of Article 12 in the Council Directive 93/42/EEC of 14 June 1993, as amended by 2007/47/EEC, concerning medical devices, the Medical Devices Act SFS 1993:584 and the Swedish Medical Product Agency regulations and guidelines: Medical Devices, LVFS 2003:11, as amended by LVFS 2009:18.

Trade Name: *Mölnlycke® Procedure Trays*

The mutual compatibility of each device within the Mölnlycke Health Care procedure packs has been verified in accordance with the relevant instructions for use provided by the manufacturer of each device and / or the approved indications for use of each device.

Where appropriate, the relevant instructions for use are provided.

Procedure packs are assembled in accordance with a documented quality management system and therefore, subject to internal controls and inspection prior to release that ensures the safety, quality and performance of the procedure pack.

Sterilisation after assembly:	*EtO, Ethylene Oxide*
CE certificate	*CE 01966*
Certificate issued by	*BSi (0086)*

For sterilised procedure packs, the sterilisation process is performed in accordance with the manufacturer(s)' instructions and follows the procedures of Annex V of 93/42/EEC.

For systems and procedure packs, the intervention of the notified body is limited to the aspects of the procedure relating to the obtaining of sterility.

Signed for and on behalf of Mölnlycke Health Care

Authorised Signatory:

Name of signing person
RA Manager, Medical Devices

Product reference	Product Name	Product Description / included devices	GMDN code
See products linked to this document in the ERP system.			

Product name, article number, manufacturer and notified body number for each device included in the system or procedure pack can be found in the BOM in the ERP system.

Signed for and on behalf of Mölnlycke Health Care

Authorised Signatory:

Name of signing person
RA Manager, Medical Devices

MÖLNLYCKE
HEALTH CARE

Göteborg 2006-08-07

To Whom It may concern:

We hereby declare that,

Following Mölnlycke Health Care surgical drapes comply with the High Performance requirements of EN13795:

- Klinidrape® laminated Patient Drapes
- BARRIER® reinforced and laminated Patient Drapes
- Klinidrape® and BARRIER® Stockinettes and plastic/laminated Leggings
- Klinidrape® and BARRIER® Table Covers and Mayo Stand Covers

Following Mölnlycke Health Care surgical drapes comply with the Standard Performance requirements of EN13795:

- Klinidrape® Utility Drapes
- BARRIER® non-reinforced Patient Drapes (less critical area)
- Klinidrape® and BARRIER® nonwoven OP-tapes (less critical area)
- Klinidrape® and BARRIER® fluid repellent Leggings and Supplementary Products (less critical area)

Mölnlycke Health Care standard Klinidrape® and BARRIER® Surgical Gowns comply with the Standard Performance requirements of EN13795.

Mölnlycke Health Care reinforced Klinidrape® and BARRIER® Surgical Gowns comply with the High Performance requirements of EN13795

Mölnlycke Health Care Clean Air Suits comply with the performance requirements of EN13795

Anders Odmyr
International Technical Support Manager
Drapes and Sets

"TEHNOMEDICA" S.R.L.

Mölnlycke Health Care AB
Box 130 80, SE 402 52 Göteborg, Sweden
Visitor: Gamlestadsvägen 3C
www.molnlycke.com
Tel: +46 31 722 30 00
Fax: +46 31 722 34 00
Reg. No 556547-5489
Seat Göteborgs Kommun

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2000

This is to certify that:

Mölnlycke Health Care AB
Gamlestadvägen 3 C
S-402 52
Göteborg
Sweden

Holds Certificate No: **FM 39247**

and operates a Quality Management System which complies with the requirements of ISO 9001:2000 for the following scope:

The design, development and manufacture of sterile wound and scar dressings, open wound products, wound management gels, cavity dressings, swabs, sponges, sterile alcohol wipes, skin care products, non sterile textile bandages and supports, sterile wound irrigation solutions, abdominal towels, operation sets, surgical and equipment drapes, procedure packs, surgical gowns and other medical staff clothing for use in the patient environment, sterile and non sterile medical gloves and sterile surgical gloves.

The design, development and manufacture of pharmaceuticals and other healthcare products.

For and on behalf of BSI:

Managing Director, BSI Management Systems (CEMEA)

Originally registered: **31/03/1998** Latest Issue: **10/01/2007**

UKAS QUALITY MANAGEMENT 003

BSI Management Systems

Certificate No: **FM 39247**

Location	***Registered Activities***
Mölnlycke Health Care AB Gamlestadsvägen 3 C S-402 52 Göteborg Sweden	The design, development and manufacture of sterile wound and scar dressings, open wound products, wound management gels, cavity dressings, swabs, sponges, sterile alcohol wipes, skin care products, non sterile textile bandages and supports, sterile wound irrigation solutions, abdominal towels, operation sets, surgical and equipment drapes, procedure packs, surgical gowns and other medical staff clothing for use in the patient environment, sterile and non sterile medical gloves and sterile surgical gloves. The design, development and manufacture of pharmaceuticals and other healthcare products.
Mölnlycke Health Care Oy PO Box 76 Saimaankatu 6 Mikkeli FIN 50101 Finland	Manufacture of swabs, sponges, towels, wound dressings, open wound products, scar dressings and procedure packs.
Mölnlycke Health Care AB Mölnlycke Health Care (Thailand) Lt 160 Bangplee Industrial Estate Bangna-Trad Rd Samutprakarn Bansaothong 10540 Thailand	Manufacture of surgical drapes and sets, equipment drapes, surgical and protective gowns and other staff clothing.
Mölnlycke Health Care AB T/A Mölnlycke Health Care SA Parc Industrial B-4300 Waremme Belgium	Manufacture of sterile drapes, operating sets and procedure packs.
Mölnlycke Health Care Klinipro s.r. Na Novem Poli 382 Prumyslova zona Karvina Karvina - State Mesto 733 01 Czech Republic	Manufacture of surgical drapes and procedure packs.

Originally registered: **31/03/1998** Latest Issue: **10/01/2007**

Certificate No: **FM 39247**

Location	***Registered Activities***
Mölnlycke Health Care AB Mölnlycke Health Care (Thailand) Lt Amata Nakorn (Bang Pakong) Industrial Estate 700/461 Moo Bangha-Trad Rd. KM.57 Tambol Donhuaroh, Amphur Muang Chonburi 20000 Thailand	Manufacture of surgical drapes and sets, equipment drapes, surgical and protective gowns and other staff clothing.
Mölnlycke Health Care AB Tubiton House Medlock Street Oldham OL1 3HS United Kingdom	The design, development and manufacture of sterile wound dressings, non sterile textile bandages and supports, procedure packs, sterile irrigation solutions, sterile alcohol wipes, skin care products, pharmaceuticals and other healthcare products.
Mölnlycke Health Care AB Lot 9, Lorong Perusahaan 4 Kulim Industrial Estate PO Box 52, 09000 Kulim Kedah Darulaman Malaysia	The design, development and manufacture of sterile and non sterile medical gloves and sterile surgical gloves.
Mölnlycke Health Care AB Plot 204 Kawasan Perindustrian Kula Ketil Phas II 09300 Kula Ketil Malaysia	The design, development and manufacture of sterile and non sterile medical gloves and sterile surgical gloves.
Mölnlycke Health Care AB Lot B5 & B6 Kawasan Perindustrian Miel Batang Kali Phase II 44300 Batang Kali Malaysia	The design, development and manufacture of sterile and non sterile medical gloves and sterile surgical gloves.

Originally registered: **31/03/1998** Latest Issue: **10/01/2007**

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Mölnlycke Health Care AB
Box 13080
Gamlestadsvägen 3C
SE-402 52 Göteborg
Sweden

Holds Certificate Number: **MD 83345**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, development, manufacture, marketing, sales and distribution of sterile wound and scar dressings, porcine collagen wound dressings, open wound products, cavity dressings, polyurethane foam with and without additives for incorporation into medical devices, swabs, sponges, sterile alcohol wipes, skin care products, non-sterile textile bandages and support, sterile wound irrigation solutions, operation sets, surgical and equipment drapes, procedure packs, surgical gowns and medical staff clothing for use in the patient environment, sterile and non-sterile medical gloves and sterile surgical gloves.
The design, development, manufacture, marketing, sales and distribution of single patient use Negative Pressure wound therapy pumps and accessories. Distribution of laparoscopic instruments.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2004-07-21
Latest Revision Date: 2018-11-26

Effective Date: 2018-11-28
Expiry Date: 2021-11-27

UKAS MANAGEMENT SYSTEMS 003

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"TEHNOMEDICA" S.R.L.

Certificate No: **MD 83345**

Location	Registered Activities
Mölnlycke Health Care AB Box 13080 Gamlestadsvägen 3C SE-402 52 Göteborg Sweden	The design, development, manufacture, marketing, sales and distribution of sterile wound and scar dressings, porcine collagen wound dressings, open wound products, cavity dressings, polyurethane foam with and without additives for incorporation into medical devices, swabs, sponges, sterile alcohol wipes, skin care products, non-sterile textile bandages and support, sterile wound irrigation solutions, operation sets, surgical and equipment drapes, procedure packs, surgical gowns and medical staff clothing for use in the patient environment, sterile and non-sterile medical gloves and sterile surgical gloves. The design, development, manufacture, marketing, sales and distribution of single patient use Negative Pressure wound therapy pumps and accessories. Distribution of laparoscopic instruments.
Molnlycke Health Care Pty Ltd Level 4 12 Narabang Way Belrose New South Wales 2085 Australia	The provision of sales, marketing, and distribution of sterile wound and scar dressings, open wound products, cavity dressings, swabs, sponges, sterile alcohol wipes, skin care products, non-sterile textile bandages and supports, sterile irrigation solutions, operation sets, surgical and equipment drapes, procedure packs, surgical gowns and other medical staff clothing for use in the patient environment, sterile and non-sterile medical gloves and sterile surgical gloves and laparoscopic instruments.

Original Registration Date: 2004-07-21
Latest Revision Date: 2018-11-26

Effective Date: 2018-11-28
Expiry Date: 2021-11-27

"TEHNOMEDICA" S.R.L.

B|BRAUN

Konformitätserklärung
Declaration of Conformity

Document-No.:	39.05.600
Revision-No.:	65
Effective Date:	2017-02-08
Page:	1 of 71

Wir | We

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

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

Kundenspezifische Sets
Zubehör Sets für Angiographie
(Artikelnummern siehe Anlage)

mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmen

Richtlinie 93/42/EWG des Rates vom 14. Juni 1993
über Medizinprodukte

Konformitätsbewertungsverfahren
nach Anhang II (ausgenommen Abschnitt 4)
nach Anhang V
der oben genannten Richtlinie

Klassifizierung
gemäß Anhang IX der
oben genannten Richtlinie
Klasse IIa / Regel 2
Klasse IIb / Regel 3
Klasse Is / Regel 2

Benannte Stelle
TÜV SÜD Product Service GmbH (ID-Nr. 0123)
Ridlerstraße 65, 80339 München, Deutschland

Datum der ersten CE-Kennzeichnung
2003-09-15

Gültig bis
2020-06-13

Berlin, 2017-02-08

B. Braun Melsungen AG

i. A.

Ralf Lorenz
Head of Quality Managment

hereby declare in our own responsibility
that the product/s

Customized Kits
Accessory Kits for Angiography
(article numbers see attachment)

is/are in compliance with the following directive

Council Directive 93/42/EEC of 14th June 1993
concerning Medical Devices

Conformity Assessment Procedure
according to annex II (excluding section 4)
according to annex V
of the Council Directive named above

Classification
according to annex IX of the
Council Directive named above
Class IIa / Rule 2
Class IIb / Rule 3
Class Is / Rule 2

Notified Body
TÜV SÜD Product Service GmbH (ID-No. 0123)
Ridlerstraße 65, 80339 Munich, Germany

Date of first CE-marking
2003-09-15

Valid until
2020-06-13

Berlin, 2017-02-08

B. Braun Melsungen AG

i. V.

Dr. Bernhard Jänicke
Head of Regulatory Affairs Management

"TEHNOMEDICA" S.R.L. IDNO 1002600053266

Art.-Nr. / Art. No.	Artikelbezeichnung	Article description	Klasse / Class
5010550	Angiodyn Angiographie Set 3-fach, OFF	Angiodyn 5ngiographic kit 3-way, OFF	IIa
5010582	Coroset Marienhospital Herne	Coroset Marienhospital Herne	IIa
5010583	Hahnbank-Set Kard. GMP Göttingen	Hahnbank-Set Kard. GMP Göttingen	IIa
5010584	Abdeck-Set Kard. GMP Göttingen	Abdeck-Set Kard. GMP Göttingen	IIa
5010585	Coro Set Hagen	Coro Set Hagen	IIa
5010592	Kalmar Pacemakerset	Kalmar Pacemakerset	IIa
5010595	Schrittmacher-Set Pirna	Schrittmacher-Set Pirna	IIa
5010602	Schrittmacherset Nordhorn	Schrittmacherset Nordhorn	IIa
5010609	Tab. Cateterismo – Hosp. Santa Marta	Tab. Cateterismo – Hosp. Santa Marta	IIa
5010622	Biopsiasetti Kymenlaakson KS, RTG	Biopsiasetti Kymenlaakson KS, RTG	IIa
5010628	Schrittmacherset HPK Dr. Natour	Schrittmacherset HPK Dr. Natour	IIa
5010635	Angiodyn Angioset EVK Hamm	Angiodyn Angioset EVK Hamm	IIa
5010637	Schrittmacher Set Helios Klinikum München West	Schrittmacher Set Helios Klinikum München West	IIa
5010646	Radialis Set EKO	Radialis Set EKO	IIa
5010647	Coro Set Marktredwitz	Coro Set Marktredwitz	IIa
5010651	Putra Medical Center, Alor Star	Putra Medical Center, Alor Star	IIa
5010660	Angiodyn Hahnbankbaugruppe 3-fach, OFF	Angiodyn manifold assembly 3-way OFF	IIa
5010662	Schrittmacher Set	Schrittmacher Set	IIa
5010687	Hahnbankset Uni Münster	Hahnbankset Uni Münster	IIa
5010690	Feinnadelset KH-Stuttgart	Feinnadelset KH-Stuttgart	IIa
5010691	Angiodyn Coroset Villingen-Schwenningen	Angiodyn Coroset Villingen-Schwenningen	IIa
5010696	Coroset Bad Pyrmont	Coroset Bad Pyrmont	IIa
5010701	Coroset Nagold	Coroset Nagold	IIa
5010709	PTCA Set	PTCA Set	IIa
5010714	Port-Punktionsset	Port-Punktionsset	IIa
5010724	Angiodyn EPU Set Kaufbeuren	Angiodyn EPU Set Kaufbeuren	IIa
5010727	Laser-Set, KSSP Aarau	Laser-Set, KSSP Aarau	IIa
5010744	Toimenpidesetti Seinäjoe ks, röntgen	Toimenpidesetti Seinäjoe ks, röntgen	IIa
5010749	Schrittmacher-Set Medinos Sonneberg	Schrittmacher-Set Medinos Sonneberg	IIa
5010794	Angiosetti PHKS, ELFYS	Angiosetti PHKS, ELFYS	IIa
5010764	Angiodynset 3FRR35 15360	Angiodynset 3FRR35 15360	IIa
5010778	Angio-Neuro-Set Heinrich-Braun-Krankenhaus	Angio-Neuro-Set Heinrich-Braun-Krankenhaus	IIa
5010782	Pädiatrie-Set Uni Homburg	Pädiatrie-Set Uni Homburg	IIa
5010783	Set steril pentru Angiografie	Set steril pentru Angiografie	IIa
5010796	Add On Kit	Add On Kit	Is

ZERTIFIKAT ◆ CERTIFICATE ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 15 04 12974 422

Manufacturer:

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

Facility(ies):

B. Braun Melsungen AG Vascular Systems
Mistelweg 2, 12357 Berlin, GERMANY

AESCULAP CHIFA Sp. z o.o.
ul. Tysiaclecia 14, 64-300 Nowy Tomysl, POLAND

B. Braun Melsungen AG Vascular Systems
Sieversufer 8, 12359 Berlin, GERMANY

Product Category(ies):

Coronary stent systems, PTCA catheters, PTA catheters,
PTCA guide wires and sets,
Probes for stimulation and electrophysiology,
Procedure Kits,
Angiography sets, manifolds, guide wires,
single use Right heart pulmonary artery catheters,
Monitoring sets for invasive physiological pressure measurement,
Introducer sheaths and sets,
Arterial puncture cannulae, arterial catheter sets

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713055006

Valid from: 2015-06-16
Valid until: 2020-06-13

642819

Date, 2015-06-18

Hans-Heiner Junker

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q5 17 03 10066 408

Holder of Certificate: **AESCULAP AG**
Am Aesculap-Platz
78532 Tuttlingen
GERMANY

Facility(ies):
AESCULAP AG
Am Aesculap-Platz, 78532 Tuttlingen,
GERMANY

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

Certification Mark:

TÜV SÜD DIN EN ISO 13485 tuv-sud.com/ps-cert

Scope of Certificate: **Design and development, production, technical service and distribution of implants, instruments, instrument management systems, containers, devices, tissue adhesives and procedure kits (for detailed information see attachment)**

Applied Standard(s):
EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713098053

Valid from: 2017-06-01
Valid until: 2020-05-31

Date, 2017-05-30

Stefan Preiß

Page 1 of 2

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

Attachment for certificate no Q5 17 03 10066 408
dated 2017-06-01

- Surgical, diagnostic and dental instruments
- Joint implants (hip, knee)
- Spinal implants
- Implants for osteosynthesis
- Neurosurgical vascular implants
- Products for ligature
- Motor systems
- Sterilization containers and accessories
- High frequency surgery devices
- Endoscopie systems
- Navigation systems
- Surgical suction pumps
- Special suture-sets
- Implants for replacement of connective tissue
- Tissue adhesives
- Vascular prostheses and accessories
- Local haemostatics
- Other surgical accessories

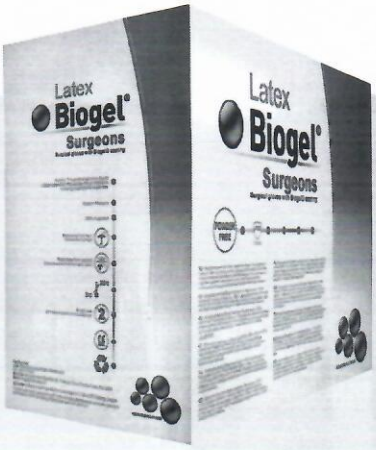
Munich, CRT2 2017-05-30

Stefan Preiß

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV®

Latex
Biogel® Surgeons



The Biogel® Surgeons is a sterile, latex surgical glove with excellent barrier protection. The unique Biogel® coating provides great fit, feel and comfort and makes the glove easy to don, even with damp hands.

ACTUAL COLOUR REF 822

Biogel® key features and benefits

- 9/10 surgeons prefer Biogel for fit, feel and comfort[1]
- Reduced chance of a hole with an industry-leading AQL* result of 0.65[1]
- Every glove (100%) is air inflation tested and visually inspected for quality and safety[1]
- Improved efficiency as less gloves are wasted[2]
- Non-pyrogenic, potentially reducing the risk of post-operative complications[3]

Recommended use

Recommended for all surgical procedures.

Material information

- Natural rubber latex
- Micro-roughened surface
- Biogel hydrogel polymer coating
- Beaded cuff
- Powder-free
- Non-pyrogenic

Biogel quality

Biogel has an industry leading freedom from holes AQL* of 0.65. The industry standard requirement for AQL* is 1.5. The lower the number, the fewer the holes and the higher the quality of glove. Biogel is proven to have the lowest glove failure rate among major competitors. Non-Biogel gloves are at least 3.5 times as likely to fail than Biogel gloves[2].

Re-order REF 822

REF	Size	Pairs
82255	5½	50/Box
82260	6	50/Box
82265	6½	50/Box
82270	7	50/Box
82275	7½	50/Box
82280	8	50/Box
82285	8½	50/Box
82290	9	40/Box

4 boxes per case

MÖLNLYCKE HEALTH CARE

Product specifications Biogel® Surgeons gloves REF 822

REF	Size	Length, mm (Tolerance +20 mm; -10 mm)	Lay flat palm width, mm (±3 mm)
82255	5.5	283	71
82260	6.0	285	77
82265	6.5	285	85
82270	7.0	288	91
82275	7.5	298	96
82280	8.0	299	103
82285	8.5	301	109
82290	9.0	301	115

Pairs per box: 50/40 for size 9

Typical thickness profile – single wall		
Cuff	8.1 mils	0.21 mm
Palm	10.0 mils	0.26 mm
Finger	10.6 mils	0.27 mm

Physical glove properties	Standard requirement	Biogel
Force at break (N) (EN455)		
Initial	≥9	19
Aged	≥9	17
Typical accelerator analysis % w/w		
Dithiocarbamate (DTC)	n/a	<0.02
Diphenyl thiourea (DPTU)	n/a	none
Diphenyl guanidine (DPG)	n/a	none
Zinc mercaptobenzothiazole (ZMBT)	n/a	none
Thiurams	n/a	none
Typical extractable protein (using Modified Lowry EN455/ ASTM D5712)	<50µg/g	<20µg/g
AQL* freedom from holes (1000 ml water leak test)	1.5	0.65
Post packing and irradiation Process average typically		<0.20%
Grip (Measure of the surface grip. Scale of 1-5, the higher the value, the greater the level of drag)	n/a	1.0

General information

Contra-indications: This product contains natural rubber latex which may cause allergic reactions including anaphylactic responses.

Allergenicity: Biogel gloves are produced to have low levels of aqueous extractable protein and have been shown to have a low potential for inducing allergic contact dermatitis or 'Type IV allergy'.

Pyrogenicity: Each batch of Biogel gloves is tested to have a low endotoxin level (<20 EU/pair).

Product standards: Biogel gloves are tested and manufactured to the following standards:

- **Quality/Environmental:** ISO 9001, ISO 13485, ISO 14001
- **Product:** ASTM D3577, EN455-1, EN455-2, EN455-3, EN455-4
- **Sterilisation:** Gamma irradiation
- **Viral Penetration:** Bacteriophage test, ASTM F1671
- **Allergenicity/Pyrogenicity:** ISO 10993 (PART 5 and 10)

Registering authority: In Europe the gloves are CE marked (notified body BSi, number 0086) indicating compliance with Council Directive 93/42/EEC. In US the gloves are FDA registered. Biogel Surgical gloves are a Class IIa Product.

Storage: Store in a cool, dry place away from sources of heat or direct sunlight.

Packaging: One pair per pack, in a high quality inner wrap, packed into a film pack (constructed of a laminate of polyester and low-density polyethylene). 50 pairs per collation case for sizes 5.5–8.5; 40 pairs for size 9.0; 200 pairs per transit case for sizes 5.5–8.5; 160 pairs for size 9.0.

Disposal: Gloves & outer wrap dispose of as clinical waste. Paper inner wrap, collation case & transit case can be recycled as paper or disposed of as clinical waste.

Shelf life: Five (5) years from date of manufacture.

Manufacturer: Made and packed in Malaysia by Mölnlycke Health Care Sdn Bhd.

Country of origin: Malaysia.

E-mail address: biogel@molnlycke.com

Date of issue: May 2012.

References: 1. Why Choose Biogel. MKT004. 2009. Data on file. 2. In Use Surgical Glove Failure Rate Comparison. Study G009-005. 2009. Data on file. 3. Biogel Endotoxin Report, Non-Pyrogenic Surgical Gloves. REPRHJV004. 2010. Data on file.

*AQL=Acceptable Quality Level refers to the maximum number of defective products that could be considered acceptable during the random sampling of an inspection, in this case freedom from holes in gloves.

Find out more at www.molnlycke.com

Mölnlycke Health Care AB, Box 13080, SE-402 52 Göteborg, Sweden.
T +46 31 722 30 00. F +46 31 722 34 00. www.molnlycke.com

MÖLNLYCKE HEALTH CARE

#39957