TEHNOMEDICA

str.Ciuflea, 38/1 MD-2001, mun. Chișinău, Moldova tel./fax: (022)601 102, 601 087
e-mail <tehnomedica_md@yahoo.com>

Către Centrul pentru Achiziții Publice
Centralizate în Sănătate

În atenția Grupului de lucru
al Licitației Publice **nr. 21019761 din 23.03.2020**

Declarație privind disponibilitatea prezentării documentelor justificative și a mostrelor

În conformitate cu prevederile art. 20 alin. (1) și alin. (8) al Legii nr. 131 din 03.07.2015 privind achizițiile publice, declarăm că, la solicitarea autorității contractante vom prezenta documentele justificative, inclusiv certificatele, în termenul indicat în partea V pct.A al DUAE prezentat.

Totodată, în decurs de 3 zile de la solicitare, vom prezenta mostrele pentru produsele ofertate în cadrul Licitației Publice nr. ocds-b3wdp1-MD-1581921874072, ID:21019761 din 23.03.2020 privind achiziționarea **Seturilor pentru operații cardiochirurgicale și Articolelor de uz medical pentru Anestezie și Terapie intensivă cardiochirurgie pentru anul 2020.**

Cu respect,

Director Tatiana Roibu

23.03.2020

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

TÜV SÜD 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

0405276881603

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

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

DAkkS CRT2 / 10.13

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

TÜV SÜD 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

I. Preiß

Stefan Preiß

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

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B|BRAUN

Declaration

The certification body of TÜV Management Service GmbH and the TÜV Product Service GmbH confirm that we,

AESCULAP AG
AM AESCULAP-PLATZ
78532 TUTTLINGEN / GERMANY

have established and are maintaining a quality management system according to

ISO 9001:2008
(Certificate Registration No.: 12 100 21724 TMS)
EN ISO 13485:2012 / AC:2012
(Certificate No.: Q1N 14 05 10066 365)

for the following area

Development, Production and Distribution of Implants, Instruments, Containers, Devices, Suture Material, Tissue Adhesives and Procedure Kits.

Furthermore we have implemented the conformity assessment procedure as per annex II, clause 3 of the Medical Device Directive 93/42/EEC of June 14th, 1993 for medical products. (EC certificate No.: G1 14 05 10066 366)

By labeling the products

Aesculap Product Groups
as per attached list

with the CE mark

we, **AESCULAP AG** confirm,
that we follow the essential requirements
according to MDD 93/42/EEC Annex I.

TUTTLINGEN, 2014-11-26

AESCULAP AG

i. V.

Thomas Marquard
Director Regulatory Affairs

i. A.

S. Maier

Sandra Maier
Regulatory Affairs

"TEHNOMEDICA" S.R.L.

B|BRAUN

Attachment to Declaration of 2014-11-26

Aesculap Product Groups
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
Endoscopic 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

"TEHNOMEDICA" S.R.L.

2014-11-26

ZERTIFIKAT ■ CERTIFICATE ■ 認證證書 ■ СЕРТИФИКАТ ■ CERTIFICADO ■ CERTIFICAT

Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

Aesculap AG

Am Aesculap-Platz, 78532 Tuttlingen, Germany
Carl-Braun-Straße 1, 34212 Melsungen, Germany

has established and applies
a Quality Management System for

Design and Development, Technical Service, Production and Distribution of Implants, Instruments, Containers, Devices, Suture Material, Tissue Adhesive and Procedure Kits

Aesculap AG Tuttlingen

- Surgical, diagnostic and dental instruments
- Joint Implants (hip, knee)
- Spinal Implants
- Implants for Osteosynthesis
- Neurosurgical Vascular Implants
- Motor systems
- Sterilization containers and accessories
- High frequency surgery devices
- Endoscopie systems
- Navigation systems
- Surgical suction pumps
- Veterinary instrumentation
- Special suture-sets
- Other surgical accessories
- Instrument Management System

Aesculap AG Melsungen

- Implants for replacement of connective tissue
- Tissue adhesive
- Vascular prostheses and accessories
- Local haemostatic

An audit was performed, Report No. **70062209**.
Proof has been furnished that the requirements according to

ISO 9001:2015

are fulfilled. The certificate is valid from **2017-06-01** until **2020-05-31**.
Certificate Registration No.: **12 100 21724 TMS**

"TEHNOMEDICA" S.R.L. IDNO 1002600052266

IAF DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-00

Product Compliance Management
Munich, 2017-04-11

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

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 010066 0426 Rev. 00

Manufacturer: **AESCULAP AG**
Am Aesculap-Platz
78532 Tuttlingen
GERMANY

Product Category(ies): **Implants, Instruments and Devices (for detailed information see attachment)**

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.: 713159626

Valid from: 2019-07-27

Valid until: 2024-05-26

Date, 2019-07-16

Stefan Preiß
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD 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 010066 0426 Rev. 00

Facility(ies):

AESCULAP AG
Am Aesculap-Platz, 78532 Tuttlingen, GERMANY

Surgical and dental instruments
Joint implants (hip, knee)
Spinal implants
Implants for osteosynthesis
Neurosurgical vascular implants
Products for ligature
Motor systems
High frequency surgery devices
Endoscopic systems
Navigation system
Surgical suction pumps
Implants for replacement of connective tissue
Vascular prostheses and accessories
and other surgical accessories
Collagen implants

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ 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 11 12974 427

Manufacturer:

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

Facility(ies):

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

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

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

B. Braun Medical (Suzhou) Co., Ltd.
No. 128 Changyang Street, Suzhou Industry Park, 215024
Suzhou, PEOPLE'S REPUBLIC OF CHINA

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.: 713067641
Valid from: 2016-01-07
Valid until: 2020-06-13

Date, 2016-01-07

Hans-Heiner Junker

04052768811233

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

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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**

...making excellence a habit.™

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

bsi.

By Royal Charter

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

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

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.