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

Digitally signed by Vidiborschii Vladimir
Date: 2019.06.25 16:49:13 EEST
Reason: MoldSign Signature
Location: Moldova

Product Service

CERTIFICATE

No. Q2N 17 11 12974 447

Holder of Certificate: **B. Braun Melsungen AG**
Carl-Braun-Str. 1
34212 Melsungen
GERMANY

Facility(ies):
B. Braun Medical Kft Production Division
Déli-Külhatár út 2-4, 3200 Gyöngyös, HUNGARY

Certification Mark:

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

Scope of Certificate: **Production of tubing sets and assemblies for sterile medical devices for fluid, blood and gas management, including moulding, extrusion, welding, heat forming, gluing, printing and packing under controlled conditions. Products include: blood lines, suction and drainage, urology, catheterization, ventilation, nutrition, transfusion/infusion/rinsing and configured customised sets.**

Applied Standard(s):
EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012
Upgrade required until 2019-03-31

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713120812

Valid from: 2018-02-28
Valid until: 2021-02-27

Date, 2018-01-17

Stefan Preiß

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Page 1 of 1

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

TÜV®

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 17 05 12974 441

Manufacturer:

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

Product Category(ies):

Active medical devices for fluid management:
- Volumetric infusion pumps
- Infusion syringe pumps
- Elastomeric Pumps
- Control & organisation units and systems made out of it
- Irrigation Pump and Accessories
- Enteral feeding pumps
- Devices for nerve Stimulation
- Pump for negative pressure wound therapy

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.: 713107933

Valid from: 2017-06-29
Valid until: 2019-10-27

04052768852892

Date, 2017-06-29

Stefan Preiß

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ 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 17 05 12974 441

Facility(ies):

B. Braun Melsungen AG
Schwarzenberger Weg 73-79, 34212 Melsungen, GERMANY

B.Braun Melsungen AG
Pfieffewiesen, 34212 Melsungen, GERMANY

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

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

B. Braun Melsungen AG
Am Buschberg 1, 34212 Melsungen, GERMANY

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

TÜV®

B BRAUN

Konformitätserklärung

Declaration of Conformity

Document-No.:	162-005
Revision-No.:	1.0
Effective Date:	Last date of signature
Page:	1 of 2

Wir

We

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

Infusomat® compact^{plus}
Volumetrische Infusionspumpe
(Artikelnummern siehe Anlage I)

Infusomat® compact^{plus}
Volumetric infusion pump
(article numbers see Attachment I)

mit den Anforderungen der folgenden Richtlinie übereinstimmt/übereinstimmen

is/are in compliance with the following directive

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

Council Directive 93/42/EEC of 14th June 1993 concerning Medical Devices amended by Directive 2007/47/EC

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

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

Klassifizierung
gemäß Anhang IX der oben genannten Richtlinie
Klasse IIb

Classification
according to annex IX of the Council Directive named above
Class IIb

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

Datum der ersten CE-Kennzeichnung
2018-03

Date of first CE-marking
2018-03

Gültig bis
2023-06-17

Valid until
2023-06-17

Melsungen, 2018-06-18

B. Braun Melsungen AG

ppa.

J. Heil
Senior Vice President Quality & Environment Management

Melsungen, 2018-06-18

B. Braun Melsungen AG

i. V.

U. Trottier
Director Regulatory Affairs CoE AIS

Anlage I / Attachment I

Art.-Nr. / Art. No.	Artikelbezeichnung / Article description	Klasse / Class
8717050	**Infusomat® compact^{plus}**	IIb

15.04.2019,ANKARA

NO: BT.2019.04.001

SUBJECT: NOTIFICATION

To whom it may concern,

CE certification audit of ÜZÜMCÜ TIBBİ CİHAZ VE MEDİKAL GAZ SİSTEMLERİ SAN. VE TİC. A.Ş. (ID: MD.3754) was conducted on 07-08-09-10-11.01.2019 according to Annex II of 93/42/EEC Medical Device Directive.

Final review for corrective and preventive actions are in progress.

For Your Information,

PS: This document has been prepared due to request of ÜZÜMCÜ TIBBİ CİHAZ VE MEDİKAL GAZ SİSTEMLERİ SAN. VE TİC. A.Ş.

Serian DOMA

Medical Device Technical Regulation Responsible

UDEM ULUSLARARASI BELGELENDİRME
UDEM DEN. EĞT. MERK. SAN. VE TİC. A.Ş.
Mutlukent Mah. 2073. Sk. No:10 Ümitköy - Çankaya / ANKARA
Tel: (0.312) 443 03 90 (pbx) Fax: (0.312) 443 03 76
DOĞANBEY Vergi Dairesi : 885 044 2587

PCA

PARTNERS CERTIFICATE ASSURANCE

Sertifika

ISO 13485:2016

ÜZÜMCÜ TIBBİ CİHAZ VE MEDİKAL GAZ SİSTEMLERİ SAN. VE TİC. A.Ş.

Oğulbey Mh. Kumludere Cd. No:1/1A Gölbaşı/Ankara/TÜRKİYE

Bu sertifika yukarıdaki kuruluşa ait tıbbi cihazlar kalite yönetim sisteminin (EN ISO 13485:2016) aşağıdaki kapsam çerçevesinde PCA Sertifikasyon tarafından onaylandığını göstermekte olup, sertifikanın geçerliliği kuruluşun yıllık gözetim denetimlerinden geçmesine ve uluslararası akreditasyon kuralları gereğince ilgili yönetim sisteminin şartlarını devam ettirmesine bağlıdır.

KAPSAM

Ameliyathane ekipmanları, yoğunbakım ve acil servis ekipmanları, hasta odası ve klinik ekipmanları, sterilizasyon ve paslanmaz çelik ekipmanları, medikal gaz sistemi ve ekipmanları, hastane, ambulans ve laboratuvarların ekipmanlarının tasarımı, geliştirilmesi, üretimi, montajı, dağıtımı ve servisi

GRUP KODU

M01-M11-MDS7006

Sertifika No	: TC-75126
Tescil Tarihi	: 06.05.2019
Yeniden Basım Tarihi	:
Geçerlilik Tarihi	: 05.05.2020
Belge Periyodu	: 3 Yıl (Tescil Tarihinden İtibaren)
Hariç Tutma	: 7.5.5/7.5.7/7.5.9.2

IAS ACCREDITED
Management Systems Certification Body
MSCB-103

PARTNERS CERTIFICATE ASSURANCE

PCA Sertifikasyon Onayı

PCA Sertifikasyon Hizmetleri Limited Şirketi
Atalar Mah. Çanakkale Caddesi No:79 D:3 Kartal / İSTANBUL
Tel: +90 216 510 63 48-49 Pbx Faks: +90 216 517 63 49
www.pca-tr.com info@pca-tr.com

PCA

PARTNERS CERTIFICATE ASSURANCE

Certificate

ISO 13485 : 2016

ÜZÜMCÜ TIBBİ CİHAZ VE MEDİKAL GAZ SİSTEMLERİ SAN. VE TİC. A.Ş.

Oğulbey Mh. Kumludere Cd. No:1/1A Gölbaşı/Ankara/TURKEY

This certificate shows that the medical devices - quality management system (EN ISO 13485:2016) of the above company was approved by PCA Certification for the following scope, the validity of the certificate depends on the company's pass the annual surveillance audits and company's maintenance the related management system conditions according to international accreditation criteria

SCOPE

Design, development, production, installation, distribution and services of operation theater equipments, intensive care unit and emergency, medical service equipments, patient room and clinical equipments, sterilization and stainless steel equipments, medical gas system and equipments, hospital, ambulance and laboratory equipment conceptions

GROUP CODE

M01-M11-MDS7006

Certificate No	: TC-75126
Registration Date	: 06.05.2019
Reissue Date	:
Expiry Date	: 05.05.2020
Certificate Period	: 3 Years (Form the date of registration)
Exclusion	: 7.5.5/7.5.7/7.5.9.2

IAS ACCREDITED
Management Systems Certification Body
MSCB-103

PARTNERS CERTIFICATE ASSURANCE

PCA Certification Approval

PCA Sertifikasyon Hizmetleri Limited Şirketi
Atalar Mah. Çanakkale Caddesi No:79 D:3 Kartal / İSTANBUL
Tel: +90 216 510 63 48-49 Pbx Faks: +90 216 517 63 49
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