AST-Medical

AST-Medical S.R.L
R.Moldova, mun.Chişinău, MD-2001
str. Ciuflea 38/1, tel/fax: 022 601 102
email: astmed@yahoo.com

Anexa nr. 8
la Documentația standard nr.115
din 15.09.2021

DECLARAŢIE
privind valabilitatea ofertei

Către IMSP Institutul de Medicină Urgentă

Stimaţi domni,

Ne angajăm să menținem oferta valabilă, privind achiziționarea *Consumabilelor neurochirurgicale* prin procedura de achiziție COP nr. ocds-b3wdp1-MD-1757500221341 din 19.09.2025, pentru o durată de 60 zile (șaizeci zile), din data deschiderii ofertelor, și ea va rămâne obligatorie pentru noi și poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării: 18.09.2025

Cu stimă,

AST-Medical SRL

Director Vladimir Roibu

(semnătura autorizată)

Digitally signed by Roibu Vladimir
Date: 2025.09.17 10:26:52 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

FIRMA "AST-MEDICAL" S.R.L.

ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de indentificare de stat - codul fiscal

1003600132970

Data înregistrării **01.03.1999**

Data eliberării **12.02.2005**

Bobeica Ion, registrator de stat

Funcția, numele, prenumele persoanei care a eliberat certificatul

Semnătura

CAMERA ÎNREGISTRĂRII DE STAT 102

MD 0022782

L.Ş.

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Implantable Class IIb Devices and Class III Devices)

No. G12 053268 0092 Rev. 00

Manufacturer: **RAUMEDIC AG**
Hermann-Staudinger-Strasse 2
95233 Helmbrechts
GERMANY

SRN Manufacturer: DE-MF-000006155

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH.
In order to place the devices on the market with CE-marking, an EU Technical Documentation Assessment Certificate pursuant to Annex IX chapter II is necessary in addition to this EU Quality Management System Certificate. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:G12 053268 0092 Rev. 00

Report No.: 713274168

Valid from: 2023-04-04
Valid until: 2028-04-03

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-04-04

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TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany
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BS-MDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Implantable Class IIb Devices and Class III Devices)

No. G12 053268 0092 Rev. 00

Classification:	Class III
Device Group:	Z120390 - VARIOUS INSTRUMENTS TO SUPPORT AND MONITOR VITAL SIGNS
Intended Purpose:	-
The validity of this certificate depends on conditions and/or is limited to the following:	./.

Revision History:

Rev.	Dated	Report	Description
00	2023-04-04	713274168	Initial issuance

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RAUMEDIC
Lifeline to Health

EG-Konformitätserklärung / **EC-Declaration of Conformity**

Der im Folgenden benannte Hersteller / The manufacturing company

RAUMEDIC AG
Hermann-Staudinger-Strasse 2
95233 Helmbrechts, Deutschland

/ RAUMEDIC AG
/ Hermann-Staudinger-Strasse 2
/ 95233 Helmbrechts, Germany

erklärt in alleiniger Verantwortung, dass die nachfolgend bezeichneten Medizinprodukte
hereby declares within exclusive responsibility that the following medical devices

Artikelnummer / Article number	**Artikel** / Article
092946-001	NEUROVENT-P NEUROVENT-P
091580-001	NEUROVENT-PX NEUROVENT-PX
092956-001	NEUROVENT NEUROVENT
091678-001	NEUROVENT-IFD-S NEUROVENT-IFD-S
091576-001	NEUROVENT mit Hülsengehäuse NEUROVENT-Sleeve Housing
092976-001	NEURODUR NEURODUR
094268-001	NEUROVENT-P-TEMP NEUROVENT-P-TEMP
091431-001	NEUROVENT-PX-TEMP NEUROVENT-PX-TEMP
094278-001	NEUROVENT-TEMP NEUROVENT-TEMP
094288-001	NEUROVENT-TEMP-IFD-S NEUROVENT-TEMP-IFD-S

Artikelnummer / Article number	**Artikel** / Article
094298-001	NEURODUR-TEMP NEURODUR-TEMP
094678-001	NEUROVENT 6F NEUROVENT 6F
095008-001	NEUROVENT-PTO NEUROVENT-PTO
095108-001	NEUROVENT-PTO 2L NEUROVENT-PTO 2L
095308-001	NEUROVENT-PTO 2L BOLT NEUROVENT-PTO 2L BOLT
095317-001	NEUROVENT-IFD-R NEUROVENT-IFD-R
095327-001	NEUROVENT-TEMP-IFD-R NEUROVENT-TEMP-IFD-R
095908-001	NEUROVENT-TO NEUROVENT-TO
096704-001	NEUROVENT VP 16 NEUROVENT VP 16
-	-

RAUMEDIC-Konformitätsgruppe Nr.: 0009
RAUMEDIC Conformity Group No.: 0009
Benennung der Konformitätsgruppe: Präzisionsdruckkatheter - Bereich Neurochirurgie
Designation of Conformity Group: Precision pressure catheters for use in Neurosurgery
Klasse: III
Class: III

entwickelt, hergestellt, geprüft und vertrieben werden in Übereinstimmung mit den Forderungen der EG-Richtlinie 93/42/EWG, Anhang I und in Übereinstimmung mit dem Konformitätsbewertungsverfahren gem. Anhang II (Zertifikat Nr.: G1 053268 0088 Rev. 00 und G7 053268 078 Rev. 01).
are developed, manufactured, tested and sold in accordance with the requirements of EC Directive 93/42/EEC, Appendix I and in accordance with the conformity assessment procedures Appendix II (Certificate No.: G1 053268 0088 Rev. 00 and G7 053268 078 Rev. 01).

Die erstmalige Erklärung der EG-Konformität erfolgte am 18. Februar 1998.
The EC-Declaration of Conformity was issued for the first time on 18th February 1998.

RAUMEDIC
Lifeline to Health

Die Einhaltung der in der Richtlinie 93/42/EWG vorgegebenen Abläufe unterliegt der Überwachung durch den "notified body"
Observance of the procedures specified in Directive 93/42/EEC is subject to monitoring by the notified body

TÜV SÜD Product Service / TÜV SÜD Product Service
Ridlerstrasse 65 / Ridlerstrasse 65
80339 München, Deutschland / 80339 Munich, Germany
Kenn-Nr.: 0123 / Ref. No.: 0123

Die RAUMEDIC AG erklärt in alleiniger Verantwortung die Konformität des oben genannten Produktes entsprechend der RoHS-Richtlinie 2011/65/EU, Anhang II und in Übereinstimmung mit EN 50581.
RAUMEDIC AG declares within exclusive responsibility the conformity of above mentioned article with the requirements of RoHS-Directive 2011/65/EU, Appendix II and EN 50581.

Helmbrechts, den 25. Februar 2022
Helmbrechts, 25th February 2022

i.V. Reiner Thiem / i.V. Reiner Thiem
Head of Regulatory Affairs / Head of Regulatory Affairs
RAUMEDIC AG / RAUMEDIC AG

raumedic

EG-Konformitätserklärung / EC-Declaration of Conformity

Der im Folgenden benannte Hersteller / The manufacturing company

RAUMEDIC AG / RAUMEDIC AG
Hermann-Staudinger-Strasse 2 / Hermann-Staudinger-Strasse 2
95233 Helmbrechts, Deutschland / 95233 Helmbrechts, Germany

erklärt in alleiniger Verantwortung, dass die nachfolgend bezeichneten Medizinprodukte
hereby declares within exclusive responsibility that the following medical devices

Artikelnummer / Article number	Artikel / Article
091688-002	BOLT KIT CH9
091868-002	BOLT KIT CH5
096026-001	BOLT KIT PTO
096076-001	BOLT KIT PTO 2L
091668-002	DRILL KIT CH9
091878-002	DRILL KIT CH5
091888-001	BOLT-DRILL KIT CH5
091898-001	BOLT-DRILL KIT CH9
092380-001	BOLT-DRILL KIT PTO
092969-001	BOLT-DRILL KIT VP 16

RAUMEDIC-Konformitätsgruppe Nr.: 0026
RAUMEDIC Conformity Group No.: 0026
Benennung der Konformitätsgruppe: Katheterisierungs-Kit - Bereich Neurochirurgie
Designation of Conformity Group: Catheterisation Kit for use in Neurosurgery
Klasse / Class: III / III

entwickelt, hergestellt, geprüft und vertrieben werden in Übereinstimmung mit den Forderungen der EG-Richtlinie 93/42/EWG, Anhang I und in Übereinstimmung mit dem Konformitätsbewertungsverfahren gem. Anhang II. Gültigkeit besitzen die zugehörigen EG-Zertifikate G1 053268 0088 Rev. 00 und G7 053268 0083 Rev. 00.
are developed, manufactured, tested and sold in accordance with the requirements of EEC Directive 93/42/EEC, Appendix I, and in accordance with the conformity assessment procedures Appendix II (Certificate-No. G1 053268 0088 Rev. 00 and G7 053268 0083 Rev. 00).

Die erstmalige Erklärung der EG-Konformität erfolgte am 08. August 2000.
The EC-Declaration of Conformity was issued for the first time on 8th August 2000.

Die Einhaltung der in der Richtlinie 93/42/EWG vorgegebenen Abläufe unterliegt der Überwachung durch den "notified body":
Observance of the procedures specified in Directive 93/42/EEC is subject to monitoring by the notified body:

TÜV SÜD Product Service / TÜV SÜD Product Service
Ridlerstrasse 65 / Ridlerstrasse 65
80339 München, Deutschland / 80339 Munich, Germany
Kenn-Nr.: 0123 / Ref. No.: 0123

Helmbrechts, den 28. März 2023
Helmbrechts, 28th March 2023

i.V. Dr. Hannes Engelhardt / i.V. Dr. Hannes Engelhardt
Head of Regulatory Affairs / Head of Regulatory Affairs
RAUMEDIC AG / RAUMEDIC AG

raumedic
Raumedic AG
Hermann-Staudinger-Str. 2
95233 Helmbrechts
Germany

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

Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 053268 0081 Rev. 04

Holder of Certificate: **RAUMEDIC AG**
Hermann-Staudinger-Strasse 2
95233 Helmbrechts
GERMANY

Certification Mark:

Scope of Certificate:

Design, development, production and sales of
- systems, components and semi-finished products made from polymer materials for medical devices and medical accessories, based on extrusion, injection moulding and assembly techniques
- precision measurement catheters with accessories
- dosing systems with accessories
- compounds for the manufacturing of products for medical applications

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). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 053268 0081 Rev. 04

Report No.: 713375637

Valid from: 2025-06-20
Valid until: 2028-03-31

Date, 2025-06-20

Christoph Dicks
Head of Certification/Notified Body

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

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

Product Service

Certificate

No. Q5 053268 0081 Rev. 04

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

RAUMEDIC AG
Hermann-Staudinger-Strasse 2, 95233 Helmbrechts, GERMANY

Design, development, production and sales of
- systems, components and semi-finished products made from polymer materials for medical devices and medical accessories, based on extrusion, injection moulding and assembly techniques
- precision measurement catheters with accessories
- dosing systems with accessories

RAUMEDIC AG
Crailsheimer Strasse 34, 91555 Feuchtwangen, GERMANY

Production and sales of
- components and semi-finished products made from polymer materials for medical devices and medical accessories, based on extrusion
- compounds for the manufacturing of products for medical applications

RAUMEDIC AG
Am Mühlgraben 10, 08297 Zwönitz, GERMANY

Design, development, production and sales of
- systems, components and semi-finished products made from polymer materials for medical devices and medical accessories, based on assembly techniques
- precision measurement catheters with accessories

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