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.Ș.

Digitally signed by Roibu Vladimir
Date: 2024.02.28 13:57:13 EET
Reason: MoldSign Signature
Location: Moldova

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 și asccesoriilor pentru sistemul de monitorizare continuă a presiunii intracraniale (PIC)*, prin procedura de achiziție COP nr. ocds-b3wdp1-MD-1708337318147, ID: 21173836 din 01.03.2024, pentru o durată de 60 zile (șaizeci zile), respectiv până la data de 01.05.2024 (ziua/luna/anul), și ea va rămâne obligatorie pentru noi și poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării: 29.02.2024

Cu stimă,

AST-Medical SRL

Director Vladimir Roibu

(semnătura autorizată)

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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 053268 0087 Rev. 00

Manufacturer:

RAUMEDIC AG
Hermann-Staudinger-Strasse 2
95233 Helmbrechts
GERMANY

Product Category(ies): **Tubings, components, tubing systems, catheters including accessories**

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.: 713155060

Valid from: 2020-03-13
Valid until: 2024-05-26

Date, 2020-03-13

Christoph Dicks
Head of Certification/Notified Body

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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 053268 0088 Rev. 00

Manufacturer:

RAUMEDIC AG
Hermann-Staudinger-Strasse 2
95233 Helmbrechts
GERMANY

Product Category(ies): **Precision pressure - and multi-parameter catheters for use in neurosurgery and compartment pressure measurement including accessories**

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.: 713155060

Valid from: 2020-03-17
Valid until: 2024-05-26

Date, 2020-03-17

Christoph Dicks
Head of Certification/Notified Body

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EC Certificate

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

No. G1 053268 0088 Rev. 00

Non-Active Accessories:	**Model:**	**Class:**
	Catheterisation-Kits for use in Neurosurgery	III
	BOLT KIT	
	DRILL KIT	
	BOLT-DRILL KIT	

Active Accessories:	**Model:**	**Class:**
	NPS3	IIb
	MPR 1 DATALOGGER	IIb
	MPR2 logO DATALOGGER	IIb
	EASY logO	IIb
	RAUMED NeuroSmart	IIb
	RAUMED NeuroSmart logO	IIb

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EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 053268 0078 Rev. 01

Manufacturer:

RAUMEDIC AG
Hermann-Staudinger-Strasse 2
95233 Helmbrechts
GERMANY

Product:

Catheters for Single Use
Precision pressure catheters, intracranial

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf.

Report no.: 713165220

Valid from: 2020-04-24
Valid until: 2023-04-10

Date, 2020-04-24

Christoph Dicks
Head of Certification/Notified Body

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TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 053268 0078 Rev. 01

Model(s): Catheters for Single Use Precision pressure catheters, intracranial, epidural, parenchymal and ventricular

Parameters:

Model:	Model-Nr.:
NEUROVENT-P	092946-001
NEUROVENT	092956-001
NEUROVENT-IFD-S	091678-001
NEUROVENT-Sleeve Housing	091576-001
NEUROVENT-P-TEMP	094268-001
NEUROVENT-TEMP	094278-001
NEUROVENT-TEMP-IFD-S	094288-001
NEUROVENT 6F	094678-001
NEUROVENT-PTO	095008-001
NEUROVENT-PTO 2L	095108-001
NEUROVENT-IFD-R	095317-001
NEUROVENT-TEMP-IFD-R	095327-001
NEUROVENT-TO	095908-001
NEUROVENT VP 16	096704-001
NEURODUR-TEMP	094298-001
NEURODUR	092976-001
NEUROVENT-PX	091580-001
NEUROVENT-PX-TEMP	091431-001
NEUROVENT-PTO 2L BOLT	095308-001

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Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 053268 0083 Rev. 00

Manufacturer:

RAUMEDIC AG
Hermann-Staudinger-Strasse 2
95233 Helmbrechts
GERMANY

Product:

Disposables for Catheterisation
Catheterisation Kit for use in Neurosurgery

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf.

Report no.: 713149442

Valid from: 2020-01-15
Valid until: 2024-05-26

Date, 2020-01-15

Christoph Dicks
Head of Certification/Notified Body

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TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 053268 0083 Rev. 00

Facility(ies):

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

Model(s):

BOLT KIT CH9, REF 091688-002
BOLT KIT CH5, REF 091868-002
BOLT KIT PTO, REF 096026-001
BOLT KIT PTO 2L, REF 096076-001
DRILL KIT CH9, REF 091668-002
DRILL KIT CH5, REF 091878-002
BOLT-DRILL KIT CH5, REF 091888-001
BOLT-DRILL KIT CH9, REF 091898-001
BOLT-DRILL KIT PTO, REF 092380-001
BOLT-DRILL KIT VP 16, REF 092969-001

Parameter:

-

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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

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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Product Service

EU Technical Documentation Assessment Certificate (MDR)

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

No. G70 053268 0089 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 drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation 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 technical documentation assessment included an assessment of the clinical evaluation assessment.
The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result.
Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH.
In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment 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:G70 053268 0089 Rev. 00

Report No.: 713216854

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

EU Technical Documentation Assessment Certificate (MDR)

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

No. G70 053268 0089 Rev. 00

Classification:	Class III
Device Group:	Z120390 - VARIOUS INSTRUMENTS TO SUPPORT AND MONITOR VITAL SIGNS
Basic UDI-DI:	40578340009NDKdrZD
Intended Purpose:	RAUMEDIC® Precision pressure catheters for use in Neurosurgery are used to directly measure brain parameters (intracranial pressure (ICP), oxygen partial pressure (ptiO2) of the interstitial fluid and/or the brain temperature (TBr)). Depending on the version, up to three of the aforementioned functions can be measured with a catheter. Some versions also make liquor drainage possible at the same time. The Precision pressure catheters for use in Neurosurgery are divided according to their application sites (parenchyma, ventricle, dura), measurement site as well as their function.
Device(s):	NEUROVENT - RAUMEDIC® Precision pressure catheters

Classification:	Class III
Device Group:	Z120390 - VARIOUS INSTRUMENTS TO SUPPORT AND MONITOR VITAL SIGNS
Basic UDI-DI:	40578340009NDKU7
Intended Purpose:	RAUMEDIC® Precision pressure catheters for use in Neurosurgery are used to directly measure brain parameters (intracranial pressure (ICP), oxygen partial pressure (ptiO2) of the interstitial fluid and/or the brain temperature (TBr)). Depending on the version, up to three of the aforementioned functions can be measured with a catheter. Some versions also make liquor drainage possible at the same time. The Precision pressure catheters for use in Neurosurgery are divided according to their application sites (parenchyma, ventricle, dura), measurement site as well as their function.
Device(s):	NEUROVENT, NEURODUR - RAUMEDIC® Precision pressure catheters

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	713216854	Initial issuance

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TÜV SÜD Product Service

EU Technical Documentation Assessment Certificate (MDR)

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

No. G70 053268 0089 Rev. 00

List of Variants for Basic UDI-DI: 40578340009NDKdrZD

Medical Device	Article Number	Basic UDI DI
NEUROVENT-Sleeve Housing	091576-001	40578340009NDKdrZD
NEUROVENT-IFD-S	091678-001	40578340009NDKdrZD
NEUROVENT	092956-001	40578340009NDKdrZD
NEUROVENT-TEMP	094278-001	40578340009NDKdrZD
NEUROVENT-TEMP-IFD-S	094288-001	40578340009NDKdrZD
NEUROVENT 6F	094678-001	40578340009NDKdrZD
NEUROVENT-IFD-R	095317-001	40578340009NDKdrZD
NEUROVENT-TEMP-IFD-R	095327-001	40578340009NDKdrZD
NEUROVENT VP 16	096704-001	40578340009NDKdrZD

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EU Technical Documentation Assessment Certificate (MDR)

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

No. G70 053268 0089 Rev. 00

List of Variants for Basic UDI-DI: 40578340009NDKU7

Medical Device	Article Number	Basic UDI DI
NEUROVENT-P	092946-001	40578340009NDKU7
NEURODUR	092976-001	40578340009NDKU7
NEUROVENT-P-TEMP	094268-001	40578340009NDKU7
NEURODUR-TEMP	094298-001	40578340009NDKU7
NEUROVENT-PTO	095008-001	40578340009NDKU7
NEUROVENT-PTO 2L	095108-001	40578340009NDKU7
NEUROVENT-TO	095908-001	40578340009NDKU7
NEUROVENT-PX	091580-001	40578340009NDKU7
NEUROVENT-PX-TEMP	091431-001	40578340009NDKU7
NEUROVENT-PTO 2L BOLT	095308-001	40578340009NDKU7

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