

Urgent safety information

Commercial name of the affected products:

Neurosurgical precision pressure catheters

Identifier (e.g. date):

NEUROVENT-/NEURODUR

Type of action:

FSN 02/2026

Date:

Field Safety Notice

September 07, 2026

Sender:

RAUMEDIC AG

Hermann-Staudinger-Str. 2
95233 Helmbrechts, Germany
Germany

Recipient:

Distributors and clinical end users of the medical devices specified below.

Details on affected devices:

The issue affects only Portuguese-language Instructions for Use (IFUs) supplied with certain neurosurgical precision pressure catheters. This language version is used exclusively in Portugal and Brazil.

Affected products are those **manufactured after 2023-08-01** (August 1, 2023), still within their approved shelf life, and corresponding to one of the catheter variants listed in the table below.

Article-No. (REF)	Name
092946-001	NEUROVENT-P
092956-001	NEUROVENT
091678-001	NEUROVENT-IFD-S
092976-001	NEURODUR
094268-001	NEUROVENT-P-TEMP
094288-001	NEUROVENT-TEMP-IFD-S
094678-001	NEUROVENT 6F
095008-001	NEUROVENT-PTO
095108-001	NEUROVENT-PTO 2L
095317-001	NEUROVENT-IFD-R
095327-001	NEUROVENT-TEMP-IFD-R

The date of manufacture as well as the catheter variant can be identified on the product label as shown in the example figure below.



catheter
variant

NEUROVENT-P

REF 092946-001

QTY 1

CE 0123



RAUMEDIC AG
Hermann-Staudinger-Strasse 2
95233 Helmbrechts, Germany
Tel.: +49(0)9252/359-0
www.RAUMEDIC.com

STERILE EO

MD

date of
manufacture

2023-01-01

2025-12-31

CH REP

QMT GmbH
Kannenbühlweg 4
CH-6280 Hochdorf
Switzerland
www.quality-mt.ch

UK REP

DELTA Surgical Ltd
Unit 10, Evolution,
Lymedale Business Park,
Newcastle under Lyme,
Staffordshire, ST5 9QF
United Kingdom
www.deltasurgical.co.uk

CN REP

注册人/生产企业: RAUMEDIC AG (诺美德科股份有限公司)
产品注册证编号: 国械注进20213070557
售后单位: 杭州沃克医疗器械有限公司
售后地址: 杭州市江干区迪凯国际3403-1
售后电话: 0571-87913852
德国制造
监测探头

UDI

(01)04057834026092
(17)251231
(21)E8347081
(11)230101

Präzisionsdruckkatheter

Precision pressure catheter

Cathéter de pression de précision

Cateteri pressione di precisione

Cateter de presión de precisión

Tiskus sluginis kateteris

Precyzyjny cewnik ciśnieniowy

Precizna spidena katetra

Katētra na plesnē mēreni tlaku

Cateter de pressão de precisão

Katēter na presnē meranie tlaku

Cateter de precizie pentru măsurarea presiunii

Precizijski tlačni kateter

Καθετήρας πίεσης ακρίβειας

Precizni tlačni kateter

Táppiszűrőkatéter

Precisiedrukkateter

Tarkkuuspainekatetri

Precisionistykkatetri

Precisionistyyk-katetrar

Precisionistyyk-kateter

Прецизен катетър за налягане

Precizios nyomáskatéter

精密压力导管

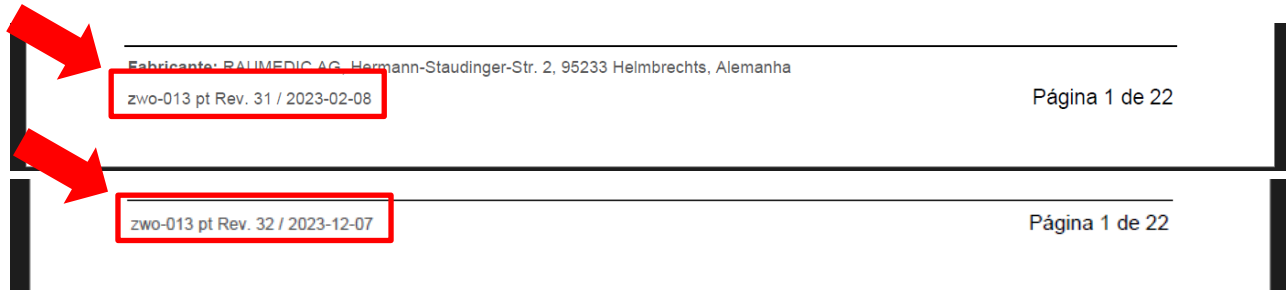
Hassas basınc kateteri

Precizni kateter pritiska

Precizni kateter pod pritiskom

The affected products have been distributed with an incorrect Portuguese-language IFU identified as **zwo-013 pt Rev. 31 / 2023-02-08** or **zwo-013 pt Rev. 32 / 2023-12-07**.

The affected IFUs can be identified by the document designation shown at the left-hand page margin (see figure below).



Description of the problem:

RAUMEDIC has identified that the Portuguese-language Instructions for Use (IFU) for neurosurgical precision pressure catheters contain translation-related inaccuracies.

1. Incorrect translation of a safety warning

In Section 16, “Warnings and Precautions”, a warning regarding the use of high-frequency (HF) surgical equipment has been translated incorrectly.

The approved English text states:

“The product is not equipped with protective measures to prevent the patient from being burnt when high-frequency surgical equipment is used.”

In the Portuguese translation, the word “not” was inadvertently omitted. As a result, the translated text may incorrectly imply that the catheter is equipped with protective measures to prevent patient burns when HF surgical equipment is used. This does not reflect the actual design, performance characteristics, or intended use of the device.

2. Outdated indication listed in the Portuguese IFU

In Section 2, “Indications”, the Portuguese-language IFU continues to list hepatic encephalopathy as an indication for use. This indication was removed from the indication purpose during the transition to Regulation (EU) 2017/745 (MDR) and is no longer included in any other language version of the IFU.

Due to an editorial oversight, this indication remained in the Portuguese translation despite having been removed from the approved indication. Consequently, the Portuguese IFU does not accurately reflect the currently approved indications for use of the device.

The identified translation errors do not affect the design, manufacture, performance, or quality of the device itself. However, reliance on the incorrect Portuguese IFU may result in users being provided with inaccurate information regarding device use and safety precautions. To date, RAUMEDIC has not received any reports of incidents, serious incidents, or injuries related to this issue.

A corrected digital version of IFU Revision 33 is available at www.raumedic.com/ifu. Physical copies of IFU Revision 33 can be requested using the enclosed reply form.

Advice on actions to be taken by the user:

- 1) Please review and understand the information provided in this letter.
- 2) Please immediately check your inventory for affected products.
- 3) If you do have affected products:
 - a) Separate the products and attach a copy of this FSN to affected products
 - b) Check the box on the enclosed form "I do have affected products" and enter the S/N of the affected products (or list the S/N in a separate table if there is insufficient space).
 - c) Please replace the affected incorrect IFU, identified as Revision 31 or Revision 32, with a physical copy of the corrected IFU, Revision 33. The corrected digital version of IFU Revision 33 can be obtained via www.raumedic.com/ifu; physical copies of IFU Revision 33 can be requested using the enclosed reply form.
- 4) If you no longer have any affected devices in your inventory, please check the box "I no longer have any affected devices".
- 5) Please return the completed reply form by email to neuromonitoring@raumedic.com. By filling the form, you confirm that you have received this Field Safety Notice and you intend to fully comply with this notification. We expect a response within 2 weeks. You also confirm that this Field Safety Notice has been forwarded to all users of the above-mentioned devices within your organisation and others who need to be informed. If you have handed over the products to third parties, please forward a copy of this information and inform the contact persons listed below.
- 6) We recommend that you retain a copy of the form for your records.

Please confirm receipt of this Field Safety Notice by using the enclosed reply form. Your organisation's response is the evidence we need to monitor the progress of the corrective action.

The Competent Authority has received a copy of this Urgent Field Safety Notice.

Contact persons

RAUMEDIC AG
Dr. Hannes Engelhardt
Head of Regulatory Affairs & Microbiology
Hermann-Staudinger-Strasse 2
95233 Helmbrechts
Germany

Telephone: +49 – (0)9252-359-1530
Mobile: +49 – (0)175 7428393
Email: Hannes.Engelhardt@raumedic.com

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Ingo Bartels
Global Vice President Clinical Products
Hermann-Staudinger-Strasse 2
95233 Helmbrechts
Germany

+49 – (0)9252-359-1431
+49 – (0)151 51798654
Ingo.Bartels@raumedic.com

Availability: Monday to Friday between 08:00 and 17:00 (CET)

The undersigned confirms that this Field Safety Notice has been notified to the Competent Regulatory Authority.

i.V. Dr Hannes Engelhardt
Head of Regulatory Affairs & Microbiology
PRRC reporting obligations Art. 15 (3)d

Field Safety Notice

Reply form

1. Safety Information	
FSN Reference Number	02/2026
FSN Date	September 07, 2026
Product information	Neurosurgical precision pressure catheters NEUROVENT-/NEURODUR
REF	092946-001
	092956-001
	091678-001
	092976-001
	094268-001
	094288-001
	094678-001
	095008-001
	095108-001
	095317-001
	095327-001

2. Customers details	
Customer	
Healthcare facility	
Address	
Department/area	
Delivery address, if different	
Contacts person	
Title or function	
Phone Number	
Email	

3. Actions carried out by the healthcare facility / distributor	
☐	I confirm receipt of the Field Safety Notice and that I have read and understood its contents
☐	The information and required actions have been communicated to all relevant users and implemented
☐	Inventory has been checked
☐	I no longer have any affected products in my inventory

☐	I have affected products																																									
☐	I would like to request _____ physical copies of the IFU (please enter the quantity).																																									
☐	Affected products have been separated and provided with a copy of this Field Safety Notice and the enclosed, incorrect IFU was replaced with a physical copy of the corrected IFU Revision 33.	<table> <tr><td>S/N:</td><td>S/N:</td></tr> <tr><td>S/N:</td><td>S/N:</td></tr> <tr><td>S/N:</td><td>S/N:</td></tr> <tr><td>S/N:</td><td>S/N:</td></tr> <tr><td>S/N:</td><td>S/N:</td></tr> <tr><td>S/N:</td><td>S/N:</td></tr> <tr><td>S/N:</td><td>S/N:</td></tr> <tr><td>S/N:</td><td>S/N:</td></tr> <tr><td>S/N:</td><td>S/N:</td></tr> <tr><td>S/N:</td><td>S/N:</td></tr> <tr><td>S/N:</td><td>S/N:</td></tr> <tr><td>S/N:</td><td>S/N:</td></tr> <tr><td>S/N:</td><td>S/N:</td></tr> <tr><td>S/N:</td><td>S/N:</td></tr> <tr><td>S/N:</td><td>S/N:</td></tr> <tr><td>S/N:</td><td>S/N:</td></tr> <tr><td>S/N:</td><td>S/N:</td></tr> <tr><td>S/N:</td><td>S/N:</td></tr> <tr><td>S/N:</td><td>S/N:</td></tr> <tr><td>S/N:</td><td>S/N:</td></tr> </table> <i>*If there is insufficient space on this form, please prepare a separate list.</i> ☐ a separate list is attached to record the S/N.	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:	S/N:
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	Name																																									
	Signature																																									
	Date																																									

4. Feedback to sender	
Email	neuromonitoring@raumedic.com
Customer Service Hotline	+49 – (0)9252-359-1587
Fax	+49 – (0)9252-359-513333
Address	RAUMEDIC AG Hermann-Staudinger Str. 2 95233 Helmbrechts Germany
Web Portals	www.raumedic.com
Deadline for returning the Customer Response Form	September 21, 2026

It is important that your organisation takes the actions listed and confirms receipt of the FSN.

Your organisation's response is the evidence we need to monitor the progress of the corrective action.