Konformitätserklärung
Declaration of Conformity

Hersteller: **GRAMM medical healthcare GmbH**
Manufacturer Werkstr. 13
DE – 71384 Weinstadt

Produkt: Actiomedic® Augenspülflasche mit Natriumchloridlösung 0,9%, 500 ml, Art. 500.000.05000
Product Actiomedic® Eye Wash Bottle with 0.9% sodium chloride solution, 500 ml , Art.: 500.000.05000

Klassifizierung: Klasse I (s) Sterilprodukt (Regel 5, Anhang IX 93/42EWG)
Device Class Class I (s) sterile product (Rule 5, Annex IX 93/42/EEC)

……

Konformitätsbewertungsverfahren:
Conformity assessment procedure
gemäß Anhang VII in Verbindung mit Anhang V der Medizinprodukte-Richtlinie 93/42/EWG
according to Annex VII in conjunction with Annex V of the Medical Device Directive (MDD) 93/42/EWG

Wir erklären in eigener Verantwortung, dass die oben genannten Produkte den Bestimmungen der Richtlinie 93/42/EWG über Medizinprodukte gerecht werden und daher den Anspruch haben, das CE-Zeichen zu tragen. Die „Grundlegenden Anforderungen" gemäß Anhang I 93/42/EWG werden erfüllt.
We hereby declare that the above mentioned products meet the provision of the Medical Device Directive (MDD) 93/42/EEC and that the products are therefore entitled to bear the CE marking. The products meet the Essential Requirements according to Annex I 93/42/EEC.

Die Überwachung erfolgt durch die benannte Stelle EG-Kenn-Nummer 0044 (TÜV NORD CERT GmbH, Am TÜV 1, 45307 Essen)
Certification and monitoring are carried out by a notified body EC No. 0044.
(TÜV NORD CERT GmbH, Am TÜV 1, 45307 Essen)

Diese Erklärung ist gültig bis zum: **26.05.2024**
This declaration is valid until

……

Freigabe / Approval
Weinstadt, den 20.05.2021
Ort, Datum
place and date

.....
Marc Sauer, GF, GRAMM medical healthcare GmbH
Unterschrift / Signature

Anhang: Gültigkeit der Konformitätserklärungen über den 26.05.2024 hinaus

Dieser Anhang dient als Ergänzung zum Confirmation Letter bezüglich der Konformitätserklärungen für Medizinprodukte. Hiermit wird bestätigt, dass alle erteilten Konformitätserklärungen für die betreffenden Produkte über den 26. Mai 2024 hinaus gültig bleiben, solange die folgenden Bedingungen erfüllt sind:

1. **Einhaltung der geltenden Normen**: Die Produkte müssen weiterhin den relevanten Normen und Richtlinien entsprechen, die zum Zeitpunkt der Erteilung der Konformitätserklärung Anwendung fanden.
2. **Änderungen am Produkt**: Sollten signifikante Änderungen am Produkt oder dessen Verwendung vorgenommen werden, muss eine neue Bewertung der Konformität durchgeführt werden.
3. **Regulatorische Vorgaben**: Die Einhaltung aller geltenden gesetzlichen und regulatorischen Vorgaben ist weiterhin Voraussetzung für die Gültigkeit der Konformitätserklärungen.

Die Hersteller sind verantwortlich für die regelmäßige Überprüfung der Konformität ihrer Produkte und sollten sich über etwaige Änderungen in der Gesetzgebung oder den Normen informieren.

Für weitere Informationen oder bei Fragen zu spezifischen Produkten steht unser Team jederzeit zur Verfügung.

Referenz EC-Certificate acc. 93/42/EEC Annex V, No.: 44 235 201680 Order 8003072301

Appendix: Validity of Declarations of Conformity Beyond May 26, 2024

This appendix serves as an addition to the Confirmation Letter regarding the Declarations of Conformity for medical devices. It is hereby confirmed that all issued Declarations of Conformity for the relevant products remain valid beyond May 26, 2024, provided that the following conditions are met:

1. ***Compliance with Applicable Standards**: The products must continue to comply with the relevant standards and regulations that were in effect at the time the Declaration of Conformity was issued.*
2. ***Changes to the Product**: Should any significant changes be made to the product or its intended use, a new conformity assessment must be conducted.*
3. ***Regulatory Requirements**: Adherence to all applicable legal and regulatory requirements remains a prerequisite for the validity of the Declarations of Conformity.*

Manufacturers are responsible for the regular review of the conformity of their products and should stay informed about any changes in legislation or standards.

For further information or if there are questions regarding specific products, our team is available at any time.

Reference: EC-Certificate acc. 93/42/EEC Annex V, No.: 44 235 201680 Order 8003072301

Weinstadt, den 07.10.2024
Ort, Datum
place and date

GRAMM medical healthcare GmbH
Unterschrift */ Signature*

TÜVNORD

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TÜV®

Our / Your Reference	Contact	Direct Dial	Date
TP: 44 235 201680; Order: 8003072301	E-Mail: medical@tuev-nord.de	Tel.: +49 201 825 2236	28 May 2024

Notified Body Confirmation Letter
Reference: EC-Certificate acc. 93/42/EEC Annex V, No.: 44 235 201680
Order 8003072301

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, TÜV NORD CERT GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0044 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

GRAMM medical healthcare GmbH
Werkstr. 13
71384 Weinstadt
Germany
SRN Number: DE-MF-000009028

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The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

i. V. Caroline Schmidt
Deputy Head of Project Management
Medical Devices International
TÜV NORD CERT GmbH
Notified Body for Medical Devices

i. V. Dr. Benjamin Hoy
TIC Manager MDR
Medical Devices International
TÜV NORD CERT GmbH
Notified Body for Medical Devices

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Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
ACTIOMEDIC® Augenspülflasche mit Natriumchloridlösung 0,9%, 250 ml	Class Is	N/A	93/42/EEC Annex V Certificate No.: 44 235 201680
ACTIOMEDIC® Augenspülflasche mit Natriumchloridlösung 0,9%, 500 ml	Class Is	N/A	93/42/EEC Annex V Certificate No.: 44 235 201680
ACTIOMEDIC® Augenspülflasche BioPhos®74 mit phosphatgepufferter Spüllösung 4,9%, 250 ml	Class Is	N/A	93/42/EEC Annex V Certificate No.: 44 235 201680
ACTIOMEDIC® Augenspülflasche mit phosphatgepufferter Spüllösung BioPhos74 4,9%, 500 ml	Class Is	N/A	93/42/EEC Annex V Certificate No.: 44 235 201680
Verbandpäckchen steril, DIN 13 151-K (klein), 60 x 80 mm	Class Is	N/A	93/42/EEC Annex V Certificate No.: 44 235 201680
Verbandpäckchen steril, DIN 13 151-M (mittel), 80 x 100 mm	Class Is	N/A	93/42/EEC Annex V Certificate No.: 44 235 201680
Verbandpäckchen steril, DIN 13 151-G (groß), 100 x 120 mm	Class Is	N/A	93/42/EEC Annex V Certificate No.: 44 235 201680
Wundkompresse steril, 50 x 50 mm	Class Is	N/A	93/42/EEC Annex V Certificate No.: 44 235 201680
Wundkompresse steril, 75 x 75 mm	Class Is	N/A	93/42/EEC Annex V Certificate No.: 44 235 201680
Wundkompressen steril, 100 x 100 mm	Class Is	N/A	93/42/EEC Annex V Certificate No.: 44 235 201680
Verbandtuch steril, DIN 13 152-BR, 400 x 600 mm	Class Is	N/A	93/42/EEC Annex V Certificate No.: 44 235 201680
Verbandtuch steril, DIN 13 152-A, 600 x 800 mm	Class Is	N/A	93/42/EEC Annex V Certificate No.: 44 235 201680
Augenkompresse steril, 50 x 70 mm	Class Is	N/A	93/42/EEC Annex V Certificate No.: 44 235 201680
Schnellverband steril, 4 x 5 cm	Class Is	N/A	93/42/EEC Annex V Certificate No.: 44 235 201680

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Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-05-20	Rev00	Initial issue