

## EU Technical Documentation Assessment Certificate

Pursuant to Regulation (EU) 2017/745 on Medical Devices,  
Annex IX, Chapter II

The Notified Body of TÜV NORD CERT GmbH certifies that the assessment of the technical documentation for the manufacturer

**HGV-Verbandstoffe GmbH**  
**Bahnhofstraße 2**  
**31698 Lindhorst**  
**Germany**

of the named device in accordance with Regulation (EU) 2017/745 Annex IX, chapter II (4) was performed during which the device was found to conform with the relevant provisions of Regulation (EU) 2017/745 for medical devices.

Any change to the approved device requires approval from the Notified Body. This Certificate by itself does not to permit to affix the CE-marking on the product, a valid certificate according to Annex IX, I and III including the products mentioned on this certificate is required in addition.

<b>Single Registration Number of the Manufacturer (SRN):</b>	DE-MF-000007886
<b>Authorised Representative:</b>	see Section 1
<b>Limitations and Conditions:</b>	see Section 2
<b>List of Products, Risk Classification and Details:</b>	see Section 3
<b>Certificate History:</b>	see Section 4

Certificate number:	44 912 220468
Certification decision report No.:	3540 0286

Valid from:	2025-12-04
Valid until:	2030-12-03
First issued:	2025-12-04
Issue date:	2025-12-04
Edition:	1

*B. Hoy*

TÜV NORD CERT GmbH is a Notified Body with identification number 0044

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### Section 1, Authorised Representative

<b>Company name:</b>	N/A
<b>Street, No.:</b>	--
<b>Postal Code, City:</b>	--
<b>Country:</b>	--

### Section 2, Limitations and Conditions

<b>The validity of this Certificate depends on:</b>	N/A
<b>and the following conditions:</b>	None
<b>and / or is limited to the following:</b>	N/A



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Section 3, List of Products, Risk Classification and Details

### CLASS III

<b>Generic device group (EMDN):</b>	M0202030101 DEVICES FOR GENERAL AND SPECIALIST DRESSINGS NON-WOVEN GAUZE PADS, WITHOUT X-RAY DETECTABLE THREAD, STERILE
<b>TD assessment report no.:</b>	3533 2945
<b>Basic UDI-DI:</b> ++B819NeurotupferM3	<b>Devices or groups of devices:</b> Neurotupfer
<b>Intended use:</b>	Exclusively for short-term use in neurosurgical skull and spinal cord procedures.
<b>Model:</b>	HGV*OP-SET* Neurotupfer 10 Stk. D = 6 mm, rund HGV*OP-SET* Neurotupfer 10 Stk. D = 8 mm, rund HGV*OP-SET* Neurotupfer 10 Stk. 6 x 10 mm HGV*OP-SET* Neurotupfer 10 Stk. 6 x 15 mm HGV*OP-SET* Neurotupfer 10 Stk. 7 x 20 mm HGV*OP-SET* Neurotupfer 10 Stk. 10 x 10 mm HGV*OP-SET* Neurotupfer 10 Stk. 10 x 15 mm HGV*OP-SET* Neurotupfer 10 Stk. 10 x 25 mm HGV*OP-SET* Neurotupfer 10 Stk. 10 x 35 mm HGV*OP-SET* Neurotupfer 10 Stk. 10 x 50 mm HGV*OP-SET* Neurotupfer 10 Stk. 10 x 75 mm HGV*OP-SET* Neurotupfer 10 Stk. 15 x 15 mm HGV*OP-SET* Neurotupfer 10 Stk. 15 x 20 mm HGV*OP-SET* Neurotupfer 10 Stk. 15 x 30 mm HGV*OP-SET* Neurotupfer 10 Stk. 15 x 60 mm HGV*OP-SET* Neurotupfer 10 Stk. 15 x 75 mm HGV*OP-SET* Neurotupfer 10 Stk. 20 x 20 mm HGV*OP-SET* Neurotupfer 10 Stk. 20 x 50 mm HGV*OP-SET* Neurotupfer 10 Stk. 20 x 60 mm HGV*OP-SET* Neurotupfer 10 Stk. 20 x 70 mm HGV*OP-SET* Neurotupfer 10 Stk. 25 x 25 mm HGV*OP-SET* Neurotupfer 10 Stk. 25 x 90 mm HGV*OP-SET* Neurotupfer 10 Stk. 30 x 60 mm HGV*OP-SET* Neurotupfer 10 Stk. 30 x 90 mm HGV*OP-SET* Neurotupfer 10 Stk. 50 x 90 mm HGV*OP-SET* Neurotupfer 10 Stk. 70 x 100 mm HGV*OP-SET* Neurotupfer 10 Stk. 70 x 100 mm, ohne Sicherheitsfaden HGV*OP-SET* Neurotupfer 10 Stk. 80 x 100 mm, ohne Sicherheitsfaden HGV*VARIO-SET* Neurotupfer-Set Nr. 075

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Section 4, Certificate History

<b>Edition</b>	<b>Date</b>	<b>Action leading to revision</b>	<b>Certification decision report No.</b>
1	2025-12-04	Initial certification	ZA 3540 0286

