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TÜV®

Our / Your Reference

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Reg. No. Under MDD:

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Date

19 June 2024

Confirmation

Certification of a Quality Management System according to (EU) 2017/745 (MDR) Ann. IX, I & III and (EU) 2017/745 Annex IX, II

TÜV NORD CERT GmbH as a notified body for medical devices under the Medical Device Regulation (EU)2017/745 herewith confirms that the company **neuro-competence GmbH** has signed the offer for a conformity procedure under (EU) 2017/745 (MDR) on 28.07.2023.

On 18.06.2024, **neuro-competence GmbH** completed and signed our form "Supplements to the application according to (EU) 2017/745 Annex VII, 4.3 (EU) 2023/607 – Specific aspects concerning the extension of time limits within the transfer of "legacy devices" to the MDR". We hereby confirm the continued surveillance according to Regulation (EU) 2023/607 by TÜV NORD CERT GmbH.

TÜV NORD CERT GmbH has received the application review documents for the products CelluStrip and SoftSurgicalStrip on 26.05.2024. The application is currently under review.

Due to the complexity of the conformity assessment procedure and the unforeseeable final decision concerning the certification neither the issuance itself nor the exact date of issuance of a certificate under the MDR can be predicted at this point.

Deputy Head of Project Management
Medical Devices International
TÜV NORD CERT GmbH

Project Management
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