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TÜV®

Date  
9 March 2026

Our / Your Reference  
30090803

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## Interim declaration Certification of a Quality Management System according to (EU) 2017/745 (MDR)

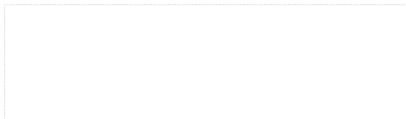
TÜV NORD CERT GmbH received the signed official application for a conformity assessment procedure under Regulation (EU) 2017/745 (MDR) dated **09 January 2024**. TÜV NORD CERT GmbH and the manufacturer have signed a written agreement in accordance with Annex VII (Section 4.3, second subparagraph) of Regulation (EU) 2017/745 (MDR). The application review was completed with a positive result, and the conformity assessment procedure has been initiated.

The final certification decision is still pending due to ongoing evaluation processes.

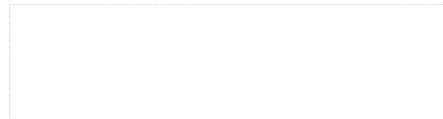
Given the complexity of the conformity assessment procedure and the currently unforeseeable outcome of the certification decision, neither the issuance nor the exact date of issuance of an MDR certificate can be predicted at this time.

Until certification according to Regulation (EU) 2017/745 (MDR) is completed, **NW-Chemie GmbH** remains under continued and appropriate surveillance.

Best regards,



**Head of Project Management**  
BE Medical  
TÜV NORD CERT GmbH  
Notified Body / Certification Body  
for Medical Devices



**Project Management**  
BE Medical  
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