

Primed Halberstadt Medizintechnik GmbH  
Straße des 20. Juli 1  
38820 Halberstadt  
Germany

Hamburg, 2022-05-17

## CONFIRMATION

Herewith we confirm that for the company

**Primed Halberstadt Medizintechnik GmbH**  
**Straße des 20. Juli 1**  
**38820 Halberstadt**  
**Germany**

the necessary audit activities to renew the certification according to EN ISO 13485:2016 have been carried out, but could not yet be completed due to high workload.

The process is currently in progress and the EN ISO 13485:2016 certificates will be issued after positive completion of the final assessment.

Regardless of this situation, the validity of the certificate provided for in Directive 93/42/EEC, Annex II (excluding section 4) and Annex V1s remains valid.

With kind regards

Lorenz Runge  
Chief Certification

