

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 757191 R000

Manufacturer: TRATE AG

Address:

Bahnhofstrasse 16
Root
6037
Switzerland

Single Registration Number: CH-MF-000019071

EU Authorised Representative: TRATE UAB

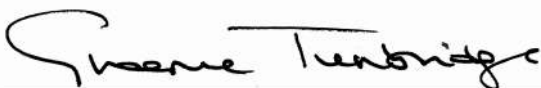
Address:

Kauno m. sav. Kauno m. Jonavos g 254
Kaunas
44110
Lithuania

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2022-08-24**

Current Issue Date: **2023-09-25**

Starting Validity Date: **2023-09-25**

Expiry Date: **2027-08-23**

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