

EU Quality Management System Certificate

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

MDR 761564 R000

Manufacturer: Braile Biomédica Indústria, Comércio e Representações Ltda.

Address:

Av. Pres. Juscelino Kubitschek de Oliveira, 1505
Jardim Tarraf I
São José do Rio Preto
São Paulo
15091-450
Brasil

Single Registration Number: BR-MF-000016583

EU Authorised Representative: Mars Medical

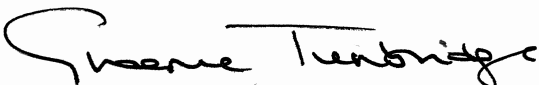
Address:

Landhausstrasse 46
70190 Stuttgart
Germany

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 Global Regulatory & Quality

First Issue Date: **2022-06-29**

Current Issue Date: **2025-03-18**

Starting Validity Date: **2025-03-18**

Expiry Date: **2027-06-28**

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Cardiopulmonary Bypass Kits and Components	Class IIa
Endoprosthesis Stent-Graft Dominus (Custom Made)	Custom-made Class III implantable
Endoprosthesis Stent-Graft Linus (Custom Made)	Custom-made Class III implantable



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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2022-06-29	3578479	Issued
Current	30388109	Supplemented – Addition of Cardiopulmonary Bypass Kits and Components to the Device Schedule



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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.