

EU Quality Management System Certificate

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

MDR 752582 R000

Manufacturer: Gauthier Biomedical, Inc.

Address:

2221 Washington St.
Grafton
Wisconsin
53024
USA

Single Registration Number: US-MF-000015766

EU Authorised Representative: Medical Device Safety Service (MDSS) GmbH

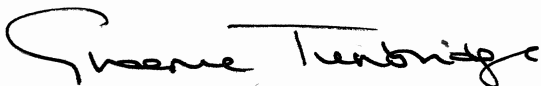
Address:

Schiffgraben 41
30175 Hannover
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 Medical Devices

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

Current Issue Date: **2023-12-11**

Starting Validity Date: **2023-12-11**

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

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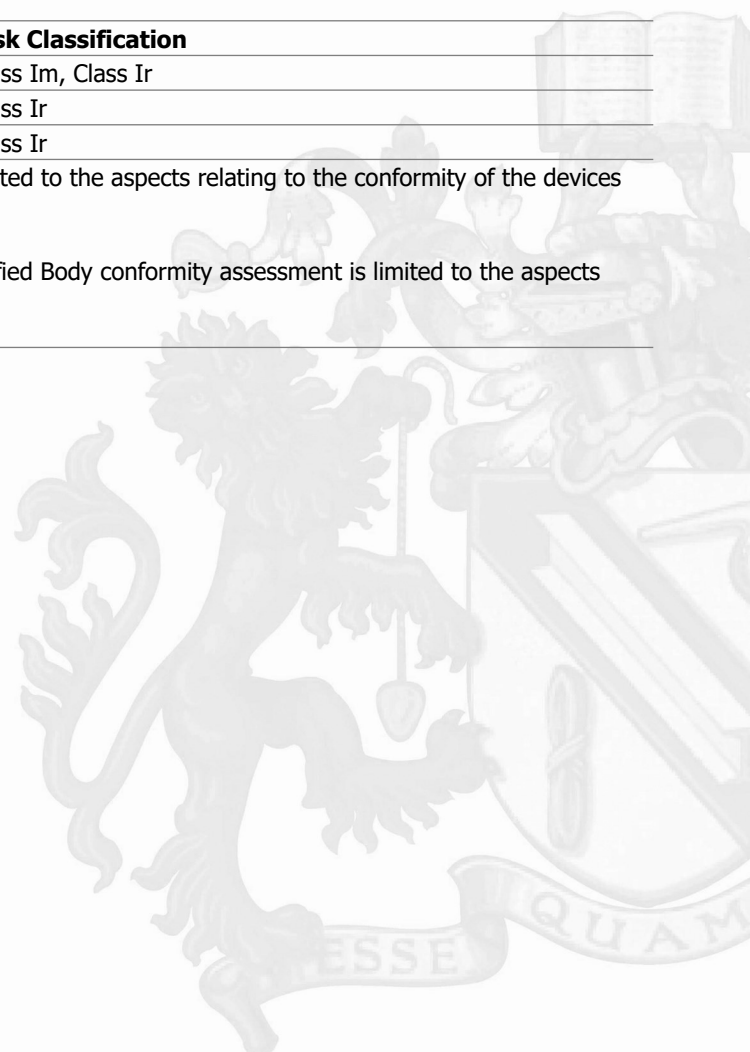
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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Reusable 'Orthopaedic Instruments' with a measuring function	Class Im, Class Ir
Reusable 'Orthopaedic Instruments'	Class Ir
Reusable 'General Surgical Retractors'	Class Ir

For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements.

For Class Ir devices (Class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device.



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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.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

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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	3480110	Issued
Current	30052795	Supplemented – Addition of Class Im, Class Ir devices "Reusable 'Orthopaedic Instruments' with a measuring function"



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