

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

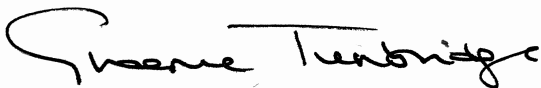
Address:

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 and Class IIb implantable devices an 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 Issued: **2022-06-29**

Date: **2022-06-29**

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

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

Device(s)	Risk Classification
Reusable Surgical Instruments 'Orthopaedic Instruments'	Class Ir
Reusable Surgical Instruments 'General Surgical Retractors'	Class Ir

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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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
Current	3480110	Issued



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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.

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