By Royal Charter

EU Quality Management System Certificate

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

MDR 760180 R000

Manufacturer: Exact Imaging Inc.

Address:
7676 Woodbine Ave
Unit 15
Markham
Ontario
L3R 2N2
Canada

Single Registration Number: CA-MF-000004363

EU Authorised Representative: Emergo Europe

Address:
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

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: **2025-03-20**

Current Issue Date: **2025-03-20**

Starting Validity Date: **2025-03-20**

Expiry Date: **2030-03-19**

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

Device(s)	Risk Classification
ExactVu High Resolution Micro-ultrasound System	Class IIa
Ultrasound Transducer	Class IIa
Sterile Transrectal Needle Guide	Class IIa
Sterile Transrectal Needle Guide Kit	Class IIa
Non-sterile Transrectal Reusable Needle Guide	Class IIa
Sterile Transperineal Needle Guide Kit	Class IIa
Sterile Transperineal Needle Guide	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	

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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	3561204	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.

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.
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