By Royal Charter

EU Quality Management System Certificate

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

MDR 740328 R000

Manufacturer: Clarius Mobile Health Corp.

Address:
205-2980 Virtual Way
Vancouver
British Columbia
V5M 4X3
Canada

Single Registration Number: Not Available

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 Medical Devices

First Issue Date: **2022-03-30**

Current Issue Date: **2023-04-20**

Starting Validity Date: **2023-04-20**

Expiry Date: **2027-03-29**

...making excellence a habit.™

By Royal Charter

EU Quality Management System Certificate

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

MDR 740328 R000

Device Schedule: Class IIa

Device(s)	Risk Classification
Clarius Ultrasound Scanner	Class IIa

First Issue Date: **2022-03-30**

Current Issue Date: **2023-04-20**

Starting Validity Date: **2023-04-20**

Expiry Date: **2027-03-29**

...making excellence a habit.™

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.

EU Quality Management System Certificate

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

MDR 740328 R000

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
2022-03-30	3331696	Issued
Current	3913631	Amended – Change of manufacturer address from 130-2985 Virtual Way, Vancouver, V5M 4X7 to 205-2980 Virtual Way, Vancouver, V5M 4X3. Amended – Change of EU Authorised Rep address from Prinsessegracht 20, 2514 AP, The Hague, The Netherlands to Westervoortsedijk 60, 6827 AT, Arnhem, The Netherlands.

First Issue Date: **2022-03-30**

Current Issue Date: **2023-04-20**

Starting Validity Date: **2023-04-20**

Expiry Date: **2027-03-29**

...making excellence a habit.™