clarius ultrasound anywhere

# Declaration of Conformity

## European Medical Device Regulations EEC 2017/745/EC

Declaration of Conformity (DoC) Number: DoC-021-2022-04-26

| **Manufacturer:** | **EC Authorized Representative** | **Registration Number** |
|---|---|---|
| | EC REP | Registration Number: MDR 740328 |
| Clarius Mobile Health Corp.<br>130-2985 Virtual Way<br>Vancouver, BC, Canada<br>V5M 4X7<br>Tel: (1) 778-800-9975 | Emergo Europe<br>Prinsessegracht 20, 2514 AP,<br>The Hague, The Netherlands<br>Tel: (31) (0) 70 345-8570<br>email: EmergoEurope@ul.com | Single Registration Number of the Manufacturer: *Not available*<br><br>Single Registration Number of the European Authorized Representative: NL-AR-000000116 |

Product Family Name**: (See Annex: Product List)**

Product Class and Rule**: (See Annex: Product List)**

(1) According to Annex IX, Chapter I and III of the Medical Device Regulation EEC 2017/745, we, Clarius Mobile Health, hereby declare under our sole responsibility that the products listed in the Product List, conform with the relevant provisions of the Medical Device Regulation EEC 2017/745.

Each of the listed and CE-marked products has been verified against defined criteria and found to be in compliance with the General Safety and Performance Requirements of Annex I in the Medical Device Regulations 2017/745 prior to being placed on the market. This declaration applies to CE Marked devices produced after the date issuance of this declaration.

The Certificate delivered by BSI Group, The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Notified Body Identification Number 2797, is in accordance with Annex IX, Chapter I and III of the Regulation EEC 2017/745.

(2) We declare, under our sole responsibility, that the products specified in the Product List also conform to the following regulations and directives. All supporting information is retained under the control of the Legal Manufacturer, Clarius Mobile Health.

- IEC 63000, Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances; RoHS2 Directive, 2011/65/EU and the RoHS3 Delegated Directive, 2015/863/EU.
- Radio Equipment Directive 2014/53/EU established under Article 3 and Article 17.

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DoC Issue Date: April 26, 2022
DoC Effective Date: April 26, 2022
Place of Issue: Vancouver, BC, Canada

Signed for on behalf of the company by:

Date: April 26, 2022

Name & Title of Signee: Agatha Szeliga
Director, Regulatory Affairs

This declaration is valid until: March 29, 2027

## Annex – Product List

The following list identifies the products by Catalogue/Model (REF) number.

Product Family: Diagnostic Ultrasound Systems and Accessories
Product/Device Trade Name: **Clarius Ultrasound Scanner**

Intended Purpose: The Clarius Ultrasound Scanner is intended for diagnostic ultrasound imaging and fluid flow analysis.

| Product Name | Catalogue/ Model Number (REF) | Applicable Rule(s) | Classification | GMDN Code | Basic UDI-DI |
|---|---|---|---|---|---|
| Clarius Scanner C3 HD | 99-13-00002 | Rule 10 and Rule 11 | Class IIa | 60924 | 7540205ClariusScannerD5 |
| Clarius Scanner L7 HD | 99-13-00004 | Rule 10 and Rule 11 | Class IIa | 60924 | 7540205ClariusScannerD5 |
| Clarius Scanner C7 HD | 99-13-00003 | Rule 10 and Rule 11 | Class IIa | 60924 | 7540205ClariusScannerD5 |
| Clarius Scanner EC7 HD | 99-13-00006 | Rule 5, 10, and Rule 11 | Class IIa | 63394 | 7540205ClariusScannerD5 |
| Clarius Scanner L15 HD | 99-13-00005 | Rule 10 and Rule 11 | Class IIa | 60924 | 7540205ClariusScannerD5 |
| Clarius Scanner PA HD | 99-13-00007 | Rule 10 and Rule 11 | Class IIa | 60924 | 7540205ClariusScannerD5 |
| Clarius Scanner L20 HD | 99-13-00014 | Rule 10 and Rule 11 | Class IIa | 60924 | 7540205ClariusScannerD5 |
| Clarius Scanner C3 HD3 | 99-13-00018 | Rule 10 and Rule 11 | Class IIa | 60924 | 7540205ClariusScannerD5 |

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|---|---|---|---|---|---|
| Clarius Scanner L7 HD3 | 99-13-00020 | Rule 10 and Rule 11 | Class IIa | 60924 | 7540205ClariusScannerD5 |
| Clarius Scanner C7 HD3 | 99-13-00019 | Rule 10 and Rule 11 | Class IIa | 60924 | 7540205ClariusScannerD5 |
| Clarius Scanner EC7 HD3 | 99-13-00024 | Rule 5, 10, and Rule 11 | Class IIa | 63394 | 7540205ClariusScannerD5 |
| Clarius Scanner L15 HD3 | 99-13-00021 | Rule 10 and Rule 11 | Class IIa | 60924 | 7540205ClariusScannerD5 |
| Clarius Scanner PA HD3 | 99-13-00023 | Rule 10 and Rule 11 | Class IIa | 60924 | 7540205ClariusScannerD5 |
| Clarius Scanner L20 HD3 | 99-13-00022 | Rule 10 and Rule 11 | Class IIa | 60924 | 7540205ClariusScannerD5 |

Refer to the Technical Documentation for a List of Standards for the device.