EXACT IMAGING

EU DECLARATION OF CONFORMITY - EU 2023/1230

Devices covered by this Declaration
ExactVu High Resolution Micro-Ultrasound System, EV-SYS-220, containing the partially completed machinery, BL1 lifting column

Manufacturer of the Products Covered by this Declaration:
Exact Imaging Inc., 7676 Woodbine Avenue, Unit 15, Markham, Ontario L3R 2N2, Canada

European Authorized Representative (AR):
Emergo Europe
Westervoortsedijk 60,
6827 AT Arnhem
The Netherlands
T: +31.(0).70.345.8570
F: +31.(0).70.346.7299
EmergoEurope@ul.com
EmergoVigilance@ul.com

Declaration
Exact Imaging Inc. declares under our sole responsibility that that the ExactVu micro-ultrasound system covered by the present Declaration is:

- In conformity with the applicable essential health and safety requirements set out in Annex III to Regulation EU 2023/1230 on machinery to the extent to which these requirements are more specific than the general safety and performance requirements set out in Annex I to Regulation EU 2017/745 on medical devices, based on the intended use of the partly completed machinery, BL1 lifting column, within the ExactVu micro-ultrasound system

The applicable essential health and safety requirements set out in Annex III of Regulation (EU) 2023/1230 on machinery are applied and fulfilled and the relevant technical documentation was drawn-up in accordance with information required by both Annex IV, Part B, and Annexes II and III to Regulation EU 2017/745 on medical devices.

Conformity to International and Harmonized Standards
Conformity is achieved by compliance to the following Harmonized Standards, where applicable to the intended use of the BL1 lifting column within the ExactVu micro-ultrasound system.

- ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes
- BS EN ISO 13485 :2016+A11:2021 Medical devices – Quality management systems – Requirements for regulatory purposes
- BS EN ISO 14971:2019+A11:2021 Medical devices – Application of risk management to medical devices
- IEC 60601-1:2005+AMD1:2012+AMD2:2020 General requirements for basic safety and essential performance
- IEC 60601-1-2:2014+AMD1:2020 (Ed. 4.0) General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances
- ISO 20417:2021 Medical devices — Information to be supplied by the manufacturer

Gwendolyn Pinto
Name of Person Responsible for Regulatory Compliance at Exact Imaging Inc.

Director, RA & QA
Title

Signature

Markham, Ontario, 2025-04-08
Place, Date of Issue

EXACT IMAGING

Revision History

Date	Author	Revision	Description of Change
Apr 8, 2025	Gwendolyn Pinto	1.0	Initial revision