GE Healthcare Global Quality Template
GEHC_RA_10.05_T001
Technical File Template

GE Healthcare

Revolution Ascend

Technical File (Technical Documentation)

In accordance with the EU Medical Device Regulation (2017/745)

Document Number: DOC2462047

Review and Approvals (minimum functional area required signatures.)

NAME	FUNCTION	SIGNATURE/DATE
Tomohiro Ito	Product RA (Author)	Refer to electric signature in MyWorkShop
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Confidentiality Statement

Digitally signed by Chicu Natalia
Date: 2022.12.16 18:20:51 EET
Reason: MoldSign Signature
Location: Moldova

Refer to the following:

Document Title	Document Number
Risk Assessment and Control	DOC0612074
Risk Management Plan	DOC2142812
Cause Mitigation Table	DOC2142815
Risk Management Summary Report	DOC2142816
e-IFU Risk Assessment/evaluation and Justification	DOC2492367 DOC2677034
FMEAs	Refer to RMP

NOTE: The above listed documents are for the latest version only. The documents for the historical all versions and other design changes are listed in DOC2481523 Revolution Ascend representative document matrix.

6. PRODUCT VERIFICATION AND VALIDATION

6.1. Pre-clinical and clinical data

6.1.a Results of Tests:

Verification and validation testing of the device has been successfully completed and demonstrate compliance to the requirements of the Medical Device Regulation (EU 2017/745), and the device specifications. Details of the testing are referenced in Section 4 (General Safety and Performance Requirements), and Section 6 (Product Verification and Validation).

Key documents not referenced elsewhere in Sections 4 and 6 include the following:

Document Title	Document Number
System (Design) Verification Plans and Reports	DOC2634853
System (Design) Validation Plan and Reports	DOC2661872
EN 60601-1-6:2010/A1:2015	DOC2424556
EN 62366-1:2015/AC:2016	DOC2423398

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6.1.b Information on Test Design, Protocols, etc.

Biocompatibility
The device or components come in Skin (A-Limited (< 24 h)):
Refer to the following report to identify the patient contacting components.