PHILIPS

Document Information
Document Identification: D000650425
Document Name: EU_MDR_DoC_Glass_Tubes
Version: C.2
Life cycle state: Approved 28-Jun-2024

Cover Sheet

Document Classification
Design Category: 3. Design Output
DMR Group Number: -

Signature Information			
Role	**Assignee**	**Vote**	**Date (DD-MMM-YYYY HH:MM:SS)**
Approver	Goettsche, Andreas	Approve	28-Jun-2024 11:05:03 UTC

Security Information		
IP Sensitivity	**Strategic Good Indicator**	**ECCN**
Internal	3 Controlled, listed in the US EAR US-origin/subject to the US EAR	EAR99

Note: The stamp below is identifying the following elements
ID number; Version; State; Document Name; DMR Group Number

D000650425;C.2;Released;EU_MDR_DoC_Glass_Tubes;-

EU Declaration of Conformity

Legal Manufacturer:
Philips Medical Systems DMC GmbH
Röntgenstraße 24
22335 Hamburg
Germany

Phone: +49 40 5078-0
www.philips.com/MedicalSystemsDMC
SRN: DE-MF-000005362

This declaration of conformity is issued under the sole responsibility of the manufacturer. The device covered by the present declaration is in conformity with all regulations below and other relevant Union legislation.

Object of the declaration:

Product Name	Product Designator/ Part Number / REF	UDI-DI	Basic UDI-DI
SRO 2550 ROT 360	9890 000 86092	00884838089969	0884838BM495TK
SRO 33100 ROT 360	9890 000 86102	00884838089945	
RO 1750 ROT 360	9890 000 86112	00884838089952	
RO 1750 ROT 350	9890 000 85282	00884838076235	
SRO 2550 ROT 350	9890 000 85831	00884838076280	
SRO 33100 ROT 350	9890 000 85841	00884838076297	
SRO 0951 ROT 350	9890 000 63182	00884838076051	
SRO 33100 ROT 380	9890 000 86482	00884838076440	
SRO 2550 ROT 380	9890 000 86471	00884838076426	
RO 1750 ROT 380	9890 000 86462	00884838076419	
DU 33100-E	9890 000 86691	00884838076495	
DU 2550-E	9890 000 86681	00884838076488	
DU 1750-E	9890 000 86671	00884838076471	
SRM 0608 ROT-GS 505	9890 000 85182	00884838076211	
SRM 2250 ROT-GS 504	9890 000 63842	00884838076099	
DA 1094 DU 694	9896 055 80930	00884838076525	
Accessories			
Not applicable			

Intended Purpose:	**Intended use** The X-ray tube assembly is an X-ray generating tube encased in a radiation-shielded housing. The X-ray tube assembly is intended to emit X-ray photons to enable the creation of diagnostic images of human patients. The X-ray tube assembly is only used as integrated part of an X-ray system and has no medical purpose by its own. The intended

D000650425;C.2;Released;EU_MDR_DoC_Glass_Tubes;-

	treatment, duration and treatment parameters are not defined on X-ray tube assembly level. This is defined by the manufacturer of the X-ray system in accordance with the intended use, the intended purpose and the medical purpose as described in the technical documentation of the X-ray system.
Control Indicator:	The DoC is valid for all serial numbers from the Start of CE Marking Date, for all part numbers mentioned in the field Product Name/ Product Designator/ Product Part Number(s).
Global Medical Device Nomenclature Code (GMDN) and Description	GMDN Code: 35618 X-ray tube housing assembly, diagnostic
CND Code : Classificazione Nazionale Dispositivi medici	Z110390 - VARIOUS DIAGNOSTIC AND INTEROPERATIVE BIOIMAGING INSTRUMENTS
Start of CE Marking according to Regulation (EU) 2017/745	May 2021, Re-issued: June 2024; Validity: 5 years
EU Authorized Representative:	Not applicable
Quality Certificates Issued:	EU Quality Management System Certificate (MDR) G10 011876 0030

The object of the declaration described above is in conformity with the following:

EU Regulation	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.
Device Risk Classification	IIb based on Annex VIII and rule 10.
Conformity Assessment Path	ANNEX IX - Conformity Assessment based on Quality Management System and assessment of Technical Documentation.
Name/Address/ID of Notified Body	TÜV Süd Product Service GmbH / Ridlerstr. 65, D-80339 München, Germany, NB ID 0123

Directive, Standards and Common Specifications	The products listed above have been tested in a typical configuration as described in the Manufacturer's accompanying documentation, and are compliant with the product standards listed below: **EN ISO 13485:2016 // EN ISO 13485:2016/A11:2021** Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) **EN 60601-1:2006 // EN 60601-1:2006/A1:2013** Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance **EN 60601-1-3:2008 // EN 60601-1-3:2008/A1:2013** Medical electrical equipment -- Part 1-3: General requirements for basic safety and essential performance - Radiation protection in diagnostic X-ray equipment **EN IEC 60601-2-28:2019** Medical electrical equipment -- Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis **EN ISO 14971:2019 // EN ISO 14971:2019/A11:2021** Medical devices - Application of risk management to medical devices **EN ISO 15223-1:2021** Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements.
Directives	The products above are compliant to the following directives: Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Signature (signed for and on behalf of Philips):
See Windchill electronic Signature on Cover page
Printed Name: **Andreas Göttsche**

Date of Issue:
See Windchill Date stamp on Cover Page
Place of Issue: **Hamburg, Germany**

Title: Head of Quality & Regulatory BC Image Chain
Person Resposible for Regulatory Compliance

D000650425_EU_MDR_DoC_Declaration_of_Conformity_Glass_Tube_Final_docx

Final Audit Report 2025-06-24

Created:	2025-06-24
By:	Mahdieiar Adeli (Mahdieiar.Adeli@philips.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAtBXBNv2cfgvk52xLCVMj3kRc-N_xv2Lp

"D000650425_EU_MDR_DoC_Declaration_of_Conformity_Glass_Tube_Final_docx" History

Document created by Mahdieiar Adeli (Mahdieiar.Adeli@philips.com)
2025-06-24 - 1:21:20 PM GMT- IP address: 151.186.20.137

Document emailed to andreas.goettsche@philips.com for signature
2025-06-24 - 1:21:46 PM GMT

Email viewed by andreas.goettsche@philips.com
2025-06-24 - 1:57:50 PM GMT- IP address: 52.102.18.5

Agreement viewed by andreas.goettsche@philips.com
2025-06-24 - 1:57:54 PM GMT- IP address: 146.112.53.182

Signer andreas.goettsche@philips.com entered name at signing as A. Göttsche
2025-06-24 - 1:58:41 PM GMT- IP address: 146.112.253.224

Document e-signed by A. Göttsche (andreas.goettsche@philips.com)
Signing reason: "I Approve"
Signature Date: 2025-06-24 - 1:58:43 PM GMT - Time Source: server- IP address: 146.112.253.224

Agreement completed.
2025-06-24 - 1:58:43 PM GMT