EC CERTIFICATION

QUALITY MANAGEMENT SYSTEM CERTIFICATE

EU Regulation 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation has been carried out following the requirements of EU Regulation 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

Certificate Number:
28620125060

Revision:
01

Initial Certification Date:
21 June 2022

Date of Certification Decision:
14 September 2023

Certificate Issue Date:
14 September 2023

Certificate Expiry Date:
31 May 2027

Agfa NV

Septestraat 27, BE-2640 Mortsel, Belgium

Manufacturer SRN: BE-MF-000000571

Scope:

- Imaging devices utilizing ionizing radiation for general, static and dynamic radiography

- Software for X-Ray systems

Brian Mather
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

PRODUCT LIST FOR CERTIFICATE

See attached Product List

EXAMINATION AND TESTS PERFORMED

Technical Assessment Report Reference	**TD0004-01 Agfa NV, DR800**
Audit Report Reference	**N/A**

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620125060	21 June 2022	Initial certificate

Certificate Number:
28620125060

Revision:
01

Initial Certification Date:
21 June 2022

Date of Certification Decision:
14 September 2023

Certificate Issue Date:
14 September 2023

Certificate Expiry Date:
31 May 2027

Brian Mather
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.