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EC CERTIFICATION

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Organization:

Agfa NV

Main Site: Septestraat 27, BE-2640 Mortsel, Belgium

Product Category:

- Devices for general radiology, mammography, extremities diagnostics and radiotherapy imaging, including oncology, neurology and cardiology

For further identification of the products covered, see the MDD product list/product schedule.

Certificate Number:
4130111178

Initial Certification Date:
9 March 2021

Certificate Valid from:
9 March 2021

Certificate Expiry Date:
26 May 2024

SWEDAC ACKREDITERING
Accred. no. 1003
Certification of Management Systems
ISO/IEC 17021-1

Peter Nermander
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

9 March 2021
Signed Date

Intertek Semko AB
Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00
medtechsweden@intertek.com

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

Intertek Semko AB is a Notified Body according to Directive 93/42/EEC on medical devices, with identification number 0413.

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AGFA NV
Septestraat 27
BE-2640 Mortsel
Belgium

26 January 2024

Notified Body Confirmation Letter
Reference: 4130111178-CN00004-34-02

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, Intertek Medical Notified Body AB, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2862 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

AGFA NV
Septestraat 27
BE-2640 Mortsel
Belgium

SRN Number: BE-MF-000000571

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR

by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Brian Mather
Certification Manager
Intertek Medical Notified Body AB

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)		MDR Device classification	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
B-UDI	Device Name			
5414904272152 XM	CR 15-X	IIa	Bermedi X-Ray B	NB 0413 - Cert No. 4130111178
			Bermedi X-Ray G	NB 0413 - Cert No. 4130111178
			CAWO DIGIT A	NB 0413 - Cert No. 4130111178
			CAWO DIGIT AL	NB 0413 - Cert No. 4130111178
			CAWO DIGIT B	NB 0413 - Cert No. 4130111178
			CAWO DIGIT BL	NB 0413 - Cert No. 4130111178
			CEA MA NEW	NB 0413 - Cert No. 4130111178
			CEA MA Plus	NB 0413 - Cert No. 4130111178
			CEA OGA	NB 0413 - Cert No. 4130111178
			CEA OGX	NB 0413 - Cert No. 4130111178
			CEA RP M	NB 0413 - Cert No. 4130111178
			CEA RX Film	NB 0413 - Cert No. 4130111178
			CEADENT DI	NB 0413 - Cert No. 4130111178
			CP-BU M	NB 0413 - Cert No. 4130111178
			CP-BU NEW	NB 0413 - Cert No. 4130111178
			Curix RP1	NB 0413 - Cert No. 4130111178
			Dentus E-Speed	NB 0413 - Cert No. 4130111178
			Dentus M2 Comfort	NB 0413 - Cert No. 4130111178
			Dentus Ortholux	NB 0413 - Cert No. 4130111178
			Dentus Ortholux Register	NB 0413 - Cert No. 4130111178
			G258	NB 0413 - Cert No. 4130111178
			Ortho CP-G Plus	NB 0413 - Cert No. 4130111178
			Ortho CP-GU	NB 0413 - Cert No. 4130111178

			Ortho CP-GU M	NB 0413 - Cert No. 4130111178
			PRIMAX RDX-58 E SOFT	NB 0413 - Cert No. 4130111178
			Primax RTG B	NB 0413 - Cert No. 4130111178
			Primax RTG G	NB 0413 - Cert No. 4130111178
			Primax RTG-B	NB 0413 - Cert No. 4130111178
			Primax RTG-G	NB 0413 - Cert No. 4130111178
			Radiolix G Plus	NB 0413 - Cert No. 4130111178
5414904272947 Z4	CR MD1.0 GENERAL PLATE	IIa	CR MD 4.0 General Plate	NB 0413 - Cert No. 4130111178
			CR MD1.0F GENERAL PLATE	NB 0413 - Cert No. 4130111178
			CR MD4.0R GENERAL PLATE	NB 0413 - Cert No. 4130111178
			CR MD4.0R GENERAL SR PLATE	NB 0413 - Cert No. 4130111178
			CR MD4.0T PLATE	NB 0413 - Cert No. 4130111178
			CR MM3.0T EXTREMITIES PLATE	NB 0413 - Cert No. 4130111178
5414904272947 Z4	CR MD1.0 GENERAL SET	IIa	CR HD5.0 AEC DETECTOR	NB 0413 - Cert No. 4130111178
			CR HD5.0 EXTREMITIES DETECTOR	NB 0413 - Cert No. 4130111178
			CR HD5.0 FLFS DETECTOR	NB 0413 - Cert No. 4130111178
			CR HD5.0 GENERAL DETECTOR	NB 0413 - Cert No. 4130111178
			CR HD5.0 GENERAL SR DETECTOR	NB 0413 - Cert No. 4130111178
			CR HD5.0S GENERAL DETECTOR	NB 0413 - Cert No. 4130111178
			CR MD1.0F GENERAL SET	NB 0413 - Cert No. 4130111178
			CR MD4.0 GENERAL SET	NB 0413 - Cert No. 4130111178
			CR MD4.0R FLFS SET	NB 0413 - Cert No. 4130111178
			CR MD4.0R GENERAL (SR) SET	NB 0413 - Cert No. 4130111178
			CR MD4.0T FLFS SET	NB 0413 - Cert No. 4130111178
			CR MD4.0T GENERAL SET	NB 0413 - Cert No. 4130111178
			CR MD4.1 FLFS SET	NB 0413 - Cert No. 4130111178
			CR MM3.0T EXTREMITIES	NB 0413 - Cert No.

			SET	4130111178
5414904272855 YW	DR 100e (Type6012/003)	IIb	DR 100e (Type6012/001)	NB 0413 - Cert No. 4130111178
5414904272855 YW	DR 100e (Type6012/004)	IIb	DR 100e (Type6012/002)	NB 0413 - Cert No. 4130111178
5414904272589 YY	DR Retrofit	IIa	CR HM5.0 MAMMO DETECTOR	NB 0413 - Cert No. 4130111178
			CR HM5.0 MAMMO DETECTOR	NB 0413 - Cert No. 4130111178
			CR MM3.0 MAMMO SET	NB 0413 - Cert No. 4130111178
			CR MM3.0 PLATE	NB 0413 - Cert No. 4130111178
			CR MM3.0R MAMMO SET	NB 0413 - Cert No. 4130111178
			CR MM3.0R PLATE	NB 0413 - Cert No. 4130111178
			CR MM3.0T MAMMO PLATE	NB 0413 - Cert No. 4130111178
			CR MM3.0T MAMMO SET	NB 0413 - Cert No. 4130111178
			Mamoray HDR-C Plus	NB 0413 - Cert No. 4130111178
			Mamoray HT	NB 0413 - Cert No. 4130111178
			PRIMAX X-MA	NB 0413 - Cert No. 4130111178
			DR 18M	NB 0413 - Cert No. 4130111178
			DR 24M	NB 0413 - Cert No. 4130111178
5414904272589 YY	DR Retrofit	IIa	DR 10e C	NB 0413 - Cert No. 4130111178
			DR 14e C	NB 0413 - Cert No. 4130111178
			DR 14e G	NB 0413 - Cert No. 4130111178
			DR 17e C	NB 0413 - Cert No. 4130111178
			DR 17e G	NB 0413 - Cert No. 4130111178
			DX-D 40C	NB 0413 - Cert No. 4130111178
			DX-D 45C	NB 0413 - Cert No. 4130111178
			DX-D 60C	NB 0413 - Cert No. 4130111178
			DX-D 60G	NB 0413 - Cert No. 4130111178
	CR 10-X	IIa		NB 0413 - Cert No. 4130111178
	CR 12-X	IIa		NB 0413 - Cert No. 4130111178

	CR 15-X	IIa		NB 0413 - Cert No. 4130111178
	CR 30Xm	IIa		NB 0413 - Cert No. 4130111178
	CR Advanced Reader	IIa		NB 0413 - Cert No. 4130111178
	CR Multiformat Reader	IIa		NB 0413 - Cert No. 4130111178
	CR Reader	IIa		NB 0413 - Cert No. 4130111178
	CR MD1.0 GENERAL PLATE	IIa		NB 0413 - Cert No. 4130111178
	CR MD1.0 GENERAL SET	IIa		NB 0413 - Cert No. 4130111178
	DR FLFS External Collimator	IIa		NB 0413 - Cert No. 4130111178

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-01-26	4130111178-CN00004-34-01	Addition of devices
2024-02-26	4130111178-CN00004-34-02	Corrections request by the manufacturer