Carestream Health, Inc.
150 Verona Street
Rochester
New York
14608
USA

07 February 2024

Notified Body Confirmation Letter

Reference: EU2023-607/640627

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, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** 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:

Carestream Health, Inc.

150 Verona Street, Rochester

14608 New York

USA

SRN Number: Not available

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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 BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

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 (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
DIRECTVIEW CR Mammography Cassette with PQ Screen	Class IIa	N/A	Certificate #CE01233; NB #2797
DIRECTVIEW CR Mammography Cassette with HR Screen	Class IIa	N/A	Certificate #CE01233; NB #2797
DIRECTVIEW CR Mammography Cassette with EHR-M3 Screen	Class IIa	N/A	Certificate #CE01233; NB #2797
CARESTREAM CR Mammography Cassette with SNP-M1 Screen	Class IIa	N/A	Certificate #CE01233; NB #2797
CR Cassette with General Purpose Phosphor Screen GP	Class IIa	N/A	Certificate #CE01233; NB #2797
CR Cassette with General Purpose Phosphor Screen GP-2	Class IIa	N/A	Certificate #CE01233; NB #2797
T-MAT G/RA Extraoral Dental Films	Class IIa	N/A	Certificate #CE01233; NB #2797
X-OMAT films	Class IIa	N/A	Certificate #CE01233; NB #2797
EVG	Class IIa	N/A	Certificate #CE01233; NB #2797
Ultra-speed	Class IIa	N/A	Certificate #CE01233; NB #2797
INSIGHT	Class IIa	N/A	Certificate #CE01233; NB #2797
D- Speed	Class IIa	N/A	Certificate #CE01233; NB #2797
E-speed	Class IIa	N/A	Certificate #CE01233; NB #2797
D88+	Class IIa	N/A	Certificate #CE01233; NB #2797
Carestream DRX-I System	Class IIa	N/A	Certificate #CE01233; NB #2797

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
Carestream DRX-Mobile Retrofit Kit	Class IIa	N/A	Certificate #CE01233; NB #2797
DRX Transportable System	Class IIa	N/A	Certificate #CE01233; NB #2797
DRX 2530C Detector	Class IIa	N/A	Certificate #CE01233; NB #2797
DRX Plus 3543 Detector	Class IIa	N/A	Certificate #CE01233; NB #2797
DRX Plus 3543C Detector	Class IIa	N/A	Certificate #CE01233; NB #2797
Lux 35	Class IIa	N/A	Certificate #CE01233; NB #2797
DRX Plus 4343 Detector	Class IIa	N/A	Certificate #CE01233; NB #2797
DRX Plus 4343C Detector	Class IIa	N/A	Certificate #CE01233; NB #2797
DRX Plus 4343F Detector	Class IIa	N/A	Certificate #CE01233; NB #2797
DRX Plus 4343FC Detector	Class IIa	N/A	Certificate #CE01233; NB #2797
Focus 35C/TRIMAX 35C Detectors	Class IIa	N/A	Certificate #CE01233; NB #2797
Focus 43C/TRIMAX 43C Detectors	Class IIa	N/A	Certificate #CE01233; NB #2797
Classic CR System	Class IIa	N/A	Certificate #CE01233; NB #2797
Vita Flex CR System	Class IIa	N/A	Certificate #CE01233; NB #2797
Trimax CR System	Class IIa	N/A	Certificate #CE01233; NB #2797
Carestream Image Suite Software	Class IIa	N/A	Certificate #CE01233; NB #2797
CARESTREAM DRX-Evolution Plus	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate #CE01233; NB #2797
DRX Compass / DR- Fit Xray System	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate #CE01233; NB #2797
Q-Rad System	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate #CE01233; NB #2797

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
DRX-Ascend System	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate
DRX-Revolution Mobile X-ray System	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate #CE01233; NB #2797
DRX-Revolution NANO Mobile X-ray System	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate #CE01233; NB #2797

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
NA	NA	NA	NA
Device 2	Choose an item.	'N/A' or Identification of the corresponding device under MDD/AIMDD	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a Notified Body certificate under Directives
Device 3	Choose an item.	'N/A' or Identification of the corresponding device under MDD/AIMDD	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a Notified Body certificate under Directives
Device 4	Choose an item.	'N/A' or Identification of the corresponding device under MDD/AIMDD	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a Notified Body certificate under Directives
Device 5	Choose an item.	'N/A' or Identification of the corresponding device under MDD/AIMDD	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a Notified Body certificate under Directives

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
Device 6	Choose an item.	'N/A' or Identification of the corresponding device under MDD/AIMDD	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a Notified Body certificate under Directives
Device 7	Choose an item.	'N/A' or Identification of the corresponding device under MDD/AIMDD	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a Notified Body certificate under Directives
Device 8	Choose an item.	'N/A' or Identification of the corresponding device under MDD/AIMDD	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a Notified Body certificate under Directives
Device 9	Choose an item.	'N/A' or Identification of the corresponding device under MDD/AIMDD	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a Notified Body certificate under Directives
Device 10	Choose an item.	'N/A' or Identification of the corresponding device under MDD/AIMDD	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a Notified Body certificate under Directives

Confirmation Letter Revision History

Date	Action
2023/06/22	Initial issue
2024/02/07	Correction of a typo in the classification for CARESTREAM DRX-Evolution Plus and DRX Compass / DR- Fit Xray System.