

Masimo Corporation
52 Discovery, Irvine,
California, 92618,
United States

4 September 2024

Notified Body Confirmation Letter

Reference: CN00182-13-03

To whom it may concern,

Certificates included:

MDD EC Certificate Annex II, G1 092076 0024 Rev 00 (NB0123)

See attached tables for details of devices.

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:

Masimo Corporation
52 Discovery, Irvine,
California, 92618,
United States

SRN Number (if available): US-MF-000010641

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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 (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
DCSC	1396	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
SpO2.com A	1774	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
SpO2.com P	1775	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
SpO2.com N	1776	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
SpO2.com I	1777	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
SpO2.com RS-I	1778	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
SpO2 disposable sensor sample pack	1851	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS Amtx	1859	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS Pmtx	1860	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS Inf-L	1861	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS Neo-L	1862	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS DCI	1863	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS DCI-P	1864	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS TC-I	1895	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS TF-I	1896	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS Amtx/Pmtx Sample Pack	1897	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS Sensor Sample Pack	1899	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS NeoPt-L	1901	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Red DCI-dc3	2053	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RED DCI-dc12	2054	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rainbow DCIP-dc-3	2069	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rainbow DCIP-dc-12	2070	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rainbow DCI-dc-3	2201	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rainbow DCI-dc-12	2202	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
R25-L	2219	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
R20-L	2220	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
R25	2221	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
R20	2222	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RED DCIP-dc3	2256	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RED DCIP-dc12	2257	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS YI	2258	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rainbow Adult Sensor Sample Pack	2291	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rainbow Ped/Inf Sensor Sample Pack	2292	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS Amtx-3	2317	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS Pmtx-3	2318	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS Inf-3	2319	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS Neo-3	2320	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS NeoPt-3	2321	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS Inf	2328	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS Neo	2329	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS NeoPt	2330	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS NeoPt-500	2331	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)

LNCS Sensor Training Kit	2345	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS Sensor Sample Pack	2346	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS Adult Sample Pack	2347	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS Neo Sample Pack	2348	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
DC-8	2387	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rainbow DCI-dc-8	2407	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS Trauma Adult	2411	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS Newborn Neo	2412	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS Newborn Infant/Pediatric	2413	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
R1 25L	2414	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
R1 20L	2415	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
M-LNCS DCI	2501	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
M-LNCS Reusable DCI-P	2502	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
M-LNCS Reusable TC-I	2503	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
M-LNCS Reusable TF-I	2504	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
M-LNCS YI	2505	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
M-LNCS Reusable DBI	2507	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
M-LNCS Adtx	2508	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
M-LNCS Adtx-3	2509	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
M-LNCS Pdtx	2510	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
M-LNCS Pdtx-3	2511	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
M-LNCS Inf	2512	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
M-LNCS Inf-3	2513	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
M-LNCS Neo	2514	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
M-LNCS Neo-3	2515	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
M-LNCS NeoPt	2516	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
M-LNCS NeoPt-3	2517	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
M-LNCS NeoPt-500	2518	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS Adtx-3	2601	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS Pdtx-3	2602	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS Inf-3	2603	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS Neo-3	2604	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS NeoPt-3	2605	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS NeoPt-500	2606	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rainbow DCIP-dc-8	2640	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RED DBI-dc3	2643	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RED DBI-dc8	2644	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rainbow DC-3 SC-200	2646	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rainbow DCP-3 SC-200	2647	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
DBI-dc3	2651	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
DBI-dc8	2652	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS DBI	2653	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
M-LNCS Sensor Sample Pack	2656	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
M-LNCS Adult Sample Pack	2657	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
M-LNCS Neo Sample Pack	2658	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
M-LNCS Sensor Training Kit	2659	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)

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Rainbow DCI	2696	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rainbow DCIP	2697	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS E1	2918	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
M-LNCS E1	2919	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS DCIV	2924	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RAS-125c	3401	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
uSpO2 Oximetry Cable, USB	3412	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rainbow DCI SC-200	3418	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rainbow DCIP SC-200	3419	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rainbow DCI SC-400	3420	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rainbow DCIP SC-400	3421	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
uSpO2 Pulse Oximetry Cable for GE ApexPro CH, CARESCAPE Telemetry T4 & T14	3449	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RAS-125c	3456	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RAS-125c	3475	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RAS-125c	3483	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
uSpO2 Oximetry Cable Assembly	3577	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Pronto	3580	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Pronto	3581	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Pronto	3582	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Pronto	3583	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Pronto	3584	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
iSpO2 Rx Adt	3588	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
iSpO2 Rx Pediatric	3590	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rainbow DCI SC-1000	3647	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rainbow DCIP SC-1000	3648	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rainbow DCI-6	3657	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RainbowDCIP-6	3658	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
M-LNCS Neo-L	3668	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
M-LNCS NeoPt-L	3669	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
M-LNCS Inf-L	3670	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
iSpO2 Rx M-LNCS	3721	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-57	3734	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-57	3735	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-57	3736	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-57	3737	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
O3 sensor	3756	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rainbow SET Intellivue Module	3777	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
R1 25	3792	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
R1 20	3793	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rainbow DCI-mini SC-200	3797	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rainbow DCI-mini SC-400	3798	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rainbow DCI-mini SC-1000	3799	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
uSpO2 Oximetry Cable, ODU	3849	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
M-LNCS TFA-I	3856	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS Red TFA-1	3857	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)

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LNCS TFA-1	3858	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
M-LNCS TFA-I	3856	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
SET Intellivue Module	3914	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
SET Intellivue Module	3915	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rainbow SET Intellivue Module	3924	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD SET Adt	4000	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD SET Pdt	4001	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD SET Inf	4002	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD SET Neo	4003	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD SET NeoPt	4004	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD SET NeoPt-500	4005	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD SET Trauma	4011	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD SET Newborn Infant/Pediatric	4012	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD SET Newborn Neonatal	4013	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD SET Blue	4014	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD SET E1	4015	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD SET TFA-1	4016	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD rainbow SET-2 Adt	4026	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD rainbow SET-2 Pdt	4027	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD rainbow SET-2 Inf	4028	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD rainbow SET-2 Neo	4029	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD rainbow Adt 8λ SpCO	4034	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD rainbow Pdt 8λ SpCO	4035	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD rainbow Inf 8λ SpCO	4036	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD rainbow Neo 8λ SpCO	4037	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD rainbow Adt 12λ SpHb SpCO	4038	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD rainbow Pdt 12λ SpHb SpCO	4039	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD rainbow Inf 12λ SpHb SpCO	4040	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD rainbow Neo 12λ SpHb SpCO	4041	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD rainbow Lite SET-1 Adt	4042	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD rainbow Lite SET-1 Pdt	4043	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD rainbow Lite SET-1 Inf	4044	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD rainbow Lite SET-1 Neo	4045	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD SET DCI	4050	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD SET DCI-P	4051	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD SET DBI	4052	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD SET TC-I	4053	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD SET YI	4054	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD TF-I	4055	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)

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LNCS-II rainbow DCI 8λ SpHb SC 200	4058	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS-II rainbow DCI 8λ SpHb SC 400	4059	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS-II rainbow DCI 8λ SpHb SC 1000	4060	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS-II rainbow DCIP 8λ SpHb SC 200	4061	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS-II rainbow DCIP 8λ SpHb SC 400	4062	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS-II rainbow DCIP 8λ SpHb SC 1000	4063	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS-II rainbow DCI 8λ SpCO	4067	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS-II rainbow DCIP 8λ SpCO	4068	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS-II rainbow DCI-6 8λ SpCO	4069	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS-II rainbow DCIP-6 8λ SpCO	4070	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RAS-45	4171	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Pronto	4175	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
rainbow SET CO-Oximetry Module	4182	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
rainbow SET CO-Oximetry Module	4183	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
rainbow SET CO-Oximetry Module	4184	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
NomoLine ISA CO2	4199	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD SET Sensor Training Kit	4201	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
rainbow SET CO-Oximetry Module	4234	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
O3 sensor	4235	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
O3 Sensor Training Kit	4273	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD Rainbow SET-2 Training Kit	4286	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RAS RRa Training Kit	4287	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Centroid	4302	Class IIa	NA	G1 092076 0024 Rev 00 (NB0123)
RD rainbow Lite SET-1 Training Kit	4303	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rainbow Super DCI-mini SC-200	4309	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rainbow Super DCI-mini SC-400	4310	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rainbow Super DCI-mini SC-1000	4311	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
O3 Pediatric Sensor Training Kit	4315	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
uSpO2 Masimo SET Oximetry Cable	4318	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
uSpO2 Oximetry Cable	4319	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
uSpO2 Masimo SET Oximetry Cable	4320	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)

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uSpO2 Oximetry Cable	4321	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
uSpO2 Masimo SET Oximetry Cable	4322	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
uSpO2 Oximetry Cable	4323	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-G sensor	4325	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rainbow Set Module	4331	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
O3 sensor	4384	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
NomoLine ISA CO2	4410	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
NomoLine ISA CO2	4412	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RAS-45 Inf/Neo	4425	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
ISA CO2	4427	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
O3 Regional Oximeter	4431	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
SedLine	4432	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-G	4469	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD SET Adt CS-2	4470	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD SET Pdt CS-2	4471	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD SET Inf CS-2	4472	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD SET Neo CS-2	4473	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD SET NeoPt CS-2	4474	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD SET Adt CS-3	4475	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD SET Pdt CS-3	4476	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD SET Inf CS-3	4477	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD SET Neo CS-3	4478	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD SET NeoPt CS-3	4479	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
O3 Regional Oximeter	4496	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
SedLine Module	4497	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rainbow Set Module	4513	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Radius PPG Adt	4582	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Radius PPG Pdt	4583	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Radius PPG Inf	4584	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Radius PPG Neo	4585	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Radius PPG reusable chip	4586	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Radius PPG wireless receiver M20	4587	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Radius PPG wireless receiver MD20	4588	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Radius PPG wireless receiver R25	4589	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD SET Adt CS-1	4615	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-G YI	4653	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS Adtx	4714	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS Pdtx/Inf/Neo Sensor Kit	4715	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
uSpO2 Masimo SET Oximetry Cable	4730	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Masimo SafetyNet	4736	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
uSpO2 Masimo SET Oximetry Cable	4775	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Radius-T Adult/Pediatric	4776	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)

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Continuous Body Temperature Sensor				
Radius PPG and Radius T for Masimo SafetyNet	4778	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Radius-T Kit for Masimo SafetyNet	4779	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Masimo Sleep	4820	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Radius VSM RAS-45	4828	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD SET Neo CS-1	4886	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Radius VSM Multi-functional Reusable Pod	4888	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Radius VSM NIBP Module	4889	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Masimo SafetyNet Alert	4898	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Masimo Sensor	4935	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
uSpO2 Masimo SET Oximetry Cable, USB	5223	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
LNCS Neo Newborn Adhesive Sensor	5265	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Radical Docking Station	9021	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Radical Docking Station	9023	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Radius VSM Kit with Reusable Pod & NIBP	9036	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Radius VSM Monitor	9037	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-57cm	9062	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Patient SafetyNet	9095	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Pronto	9167	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Radical Docking Station	9171	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Radical Docking Station	9172	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-57c	9179	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-57cm	9180	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-8, horizontal	9192	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-8, vertical	9193	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-5	9196	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-5v	9197	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-5	9198	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-5v	9199	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-G	9210	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-5	9214	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-5v	9215	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-57	9216	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-57	9217	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-5	9234	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-5v	9235	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
uSpO2 Pulse Oximetry Cable for GE ApexPro CH, CARESCAPE Telemetry T4 & T14 with LNCS Sensor Sample Pack	9476	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)

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Radical-7	9500	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
SedLine	9513	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Root	9515	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-5v	9540	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
iSpO2 Rx M-LNCS	9569	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
iSpO2 Rx Adt	9575	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
iSpO2 Rx Pediatric	9576	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
iSpO2 Rx M-LNCS	9577	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
iSpO2 Rx Adt	9578	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
iSpO2 Rx Pediatric	9579	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
O3 Regional Oximeter	9637	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Radius-7	9664	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Root	9695	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
MightySat Rx	9707	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-5v	9711	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-97	9738	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-97	9738	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
SatShare	9756	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Pronto	9757	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-97	9783	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-97	9784	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-97	9785	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-67	9794	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-97	9796	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-97	9797	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-97	9798	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-97	9799	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-97	9802	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
MightySat Rx	9807	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
MightySat Rx	9809	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Sedline Module	9829	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-G	9847	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-G	9849	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Replica	9863	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-G	9895	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
MightySat	9901	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Radius-7	9903	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
MightySat Rx	9907	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Radius-7	9916	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Nomoline ISA CO2	9921	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Radius PPG Kit, Adt	9954	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Radius PPG Kit, Neo	9955	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-97	9997	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Rad-97	95004	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Masimo W1	95080	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Masimo SET Module, RD	99028	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Masimo SET Module, LNC	99029	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
iSpO2 Rx, USB-C, Adult	99030	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
iSpO2 Rx, USB-C, Pediatric	99031	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
iSpO2 Rx, USB-C, RD	99032	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Radius PPG Chip	5276	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
Home Health Kit	95042	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)
RD SET CS Training Kit	4617	Class IIb	NA	G1 092076 0024 Rev 00 (NB0123)

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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
None			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
26 May 2024	CN00182-13	Initial email
23 August 2024	CN00182-13-01	Correction of certificate detail
1 September 2024	CN00182-13-02	Reissue following completion of tripartite agreement
4 September 2024	CN00182-13-03	Clarification of table 2