

EC Certificate

Full Quality Assurance System MDD Annex II excl. 4

Registration No.: HD 2102042-1

Manufacturer: OMRON HEALTHCARE Co., Ltd.
53, Kunotsubo, Terado-cho,
Muko, KYOTO
617-0002 JAPAN

Products:

- Electronic Sphygmomanometers
- Clinical Electronic Thermometers
- Ear Thermometers
- Infrared Forehead Thermometers
- Nebulizers
- Electroanalgesic Transcutaneous Stimulators
- Electroanalgesic Transcutaneous Stimulation Electrodes
- Cardio Vascular Profiling Systems
- Wheeze Detectors
- Electronic Sphygmomanometers with Electrocardiograph function
- Application Program Software for Electrocardiogram
- Application Program Software for Hypertension Analysis and Reporting

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 150230275-730

Effective date: 2021-02-09

Expiry date: 2024-03-21

Issue date: 2021-02-09



Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 2102042-1

Manufacturer: OMRON HEALTHCARE Co., Ltd.
53, Kunotsubo, Terado-cho,
Muko, KYOTO
617-0002 JAPAN

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	OMRON HEALTHCARE Co., Ltd. Matsusaka Factory 1855-370, Kubo-cho, Matsusaka-shi, Mie, 515-8503 Japan	Manufacturing of - Electronic Sphygmomanometers - Clinical Electronic Thermometers - Ear Thermometers - Infrared Forehead Thermometers - Nebulizers - Electroanalgesic Transcutaneous Stimulators - Electroanalgesic Transcutaneous Stimulation Electrodes - Cardio Vascular Profiling Systems - Electronic Sphygmomanometers with Electrocardiograph function

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TÜV Rheinland LGA Products GmbH • 51105 Köln

OMRON HEALTHCARE Co., Ltd.
53, Kunotsubo, Terado-cho,
Muko, KYOTO,
617-0002 JAPAN

Contact

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Date February 22, 2024

Notified Body Confirmation Letter

Reference. : OHQ_CL607_2024-02-22

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 **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** 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:

OMRON HEALTHCARE Co., Ltd.
53, Kunotsubo, Terado-cho,
Muko, KYOTO,
617-0002 JAPAN
SRN Number: JP-MF-000007213

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 under the applicable Directive.

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:

- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function

On behalf of the Notified Body


Michiaki Aihara
Certification body

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Chairman of the
Supervisory Board

Dr.-Ing. Michael Fübi

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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
No.2: Clinical Electronic Thermometers: Eco Temp Basic(MC-246-E)	Class IIa	N/A (No.465)	HD 2102042-1: NB 0197
No.3: Ear Thermometers: Gentle Temp 520 (MC-520-E)	Class IIa	N/A (No.483)	HD 2102042-1: NB 0197
No.4: Infrared Forehead Thermometers: Gentle Temp 720 (MC-720-E)	Class IIa	N/A (No.489)	HD 2102042-1: NB 0197
No.5: Electronic Sphygmomanometers: EVOLV (HEM-7600T-E)	Class IIa	N/A (No.423)	HD 2102042-1: NB 0197
No.6: Electronic Sphygmomanometers: M2 Classic (HEM-7122-ALRU)	Class IIa	N/A (No.299)	HD 2102042-1: NB 0197
No.8: Nebulizers: MicroAIR U100 (NE-U100-E)	Class IIa	N/A (No.136)	HD 2102042-1: NB 0197
No.9: Nebulizers: C21 basic (NE-C803-RU)	Class IIa	N/A (No.89)	HD 2102042-1: NB 0197
No.10: Nebulizers: NE-C803 (NE-C803-E)	Class IIa	N/A (No.86)	HD 2102042-1: NB 0197
No.11: Electroanalgesic Transcutaneous Stimulators: HeatTens (HV-F311-E)	Class IIa	N/A (No.149)	HD 2102042-1: NB 0197
No.12: Electroanalgesic Transcutaneous Stimulation Electrodes: Long Life Pads (HV-LLPAD-E)	Class IIa	N/A (No.148)	HD 2102042-1: NB 0197
No.14: Application Program Software for Hypertension Analysis and Reporting: Hypertension Plus	Class IIa	N/A (No.493)	HD 2102042-1: NB 0197
No.15: Wheeze Detectors: WheezeScan (HWZ-1000T-E)	Class IIa	N/A (No.492)	HD 2102042-1: NB 0197
No.16: Electronic Sphygmomanometers with Electrocardiograph function: Complete (HEM-7530T-E3)	Class IIa	N/A (No.152)	HD 2102042-1: NB 0197
No.24: Nebulizers: NE-C801 (NE-C801S-E(V))	Class IIa	N/A (No.49)	HD 2102042-1: NB 0197
No.25: Nebulizers: NE-C801KD (NE-C801S-KDE(V))	Class IIa	N/A (No.60)	HD 2102042-1: NB 0197
No.26: Nebulizers: NE-C801 (NE-C801S-UK(V))	Class IIa	N/A (No.51)	HD 2102042-1: NB 0197
No.27: Nebulizers: NE-C803 (NE-C803-UK)	Class IIa	N/A (No.90)	HD 2102042-1: NB 0197
No.28: Nebulizers: NE-C900 (NE-C900-E)	Class IIa	N/A (No.91)	HD 2102042-1: NB 0197
No.29: Nebulizers: NE-U780 (NE-U780-E)	Class IIa	N/A (No.125)	HD 2102042-1: NB 0197
No.30: Nebulizers: NE-C28	Class IIa	N/A (No.1)	HD 2102042-1: NB 0197
No.31: Nebulizers: NE-C801	Class IIa	N/A (No.27)	HD 2102042-1: NB 0197
No.32: Nebulizers: NE-C801	Class IIa	N/A (No.28)	HD 2102042-1: NB 0197
No.33: Nebulizers: NE-C801	Class IIa	N/A (No.63)	HD 2102042-1: NB 0197
No. 34: Nebulizers: NE-C803	Class IIa	N/A (No.82)	HD 2102042-1: NB 0197
No.35: Nebulizers:	Class IIa	N/A (No.100)	HD 2102042-1:

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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
NE-C900			NB 0197
No.36: Nebulizers: NE-U780	Class IIa	N/A (No.124)	HD 2102042-1: NB 0197
No.37: Nebulizers: Compressor Nebulizer NE-C28	Class IIa	N/A (No.13)	HD 2102042-1: NB 0197
No.38: Nebulizers: NE-U100	Class IIa	N/A (No.123)	HD 2102042-1: NB 0197
No.39: Nebulizers: NE-C101	Class IIa	N/A (No.19)	HD 2102042-1: NB 0197
No.40: Nebulizers: NE-C101	Class IIa	N/A (No.20)	HD 2102042-1: NB 0197
No.41: Nebulizers: NE-C106	Class IIa	N/A (No.24)	HD 2102042-1: NB 0197
No.42: Nebulizers: NEB-NSET3-82 (NEB-NSET3-82E)	Class IIa	N/A (No.73)	HD 2102042-1: NB 0197
No.43: Nebulizers: Supply medication set	Class IIa	N/A (No.105)	HD 2102042-1: NB 0197
No.44: Nebulizers: U12-1-E	Class IIa	N/A (No.104)	HD 2102042-1: NB 0197
No.45: Nebulizers: U17-4P2-E	Class IIa	N/A (No.115)	HD 2102042-1: NB 0197
No.46: Nebulizers: Adapter (U17-13P2-E)	Class IIa	N/A (No.114)	HD 2102042-1: NB 0197
No.47: Nebulizers: NEB-NSET3-81 (NEB-NSET3-81E)	Class IIa	N/A (No.33)	HD 2102042-1: NB 0197
No.48: Nebulizers: NEB-NSET3-83E	Class IIa	N/A (No.87)	HD 2102042-1: NB 0197
No.49: Nebulizers: NEB-NSET3-90 (NEB-NSET3-90E)	Class IIa	N/A (No.93)	HD 2102042-1: NB 0197
No.50: Nebulizers: NEB-MP (NEB-MP-E)	Class IIa	N/A (No.42)	HD 2102042-1: NB 0197
No.51: Nebulizers: NEB-NP (NEB-NP-E)	Class IIa	N/A (No.44)	HD 2102042-1: NB 0197
No.52: Nebulizers: NEB-MSSP (NEB-MSSP-E)	Class IIa	N/A (No.97)	HD 2102042-1: NB 0197
No.53: Nebulizers: NEB-MSMP (NEB-MSMP-E)	Class IIa	N/A (No.37)	HD 2102042-1: NB 0197
No.54: Nebulizers: NEB-MSLP (NEB-MSLP-E)	Class IIa	N/A (No.35)	HD 2102042-1: NB 0197
No.55: Nebulizers: Child Mask(SEBS)set (NEB-MSSS-E)	Class IIa	N/A (No.40)	HD 2102042-1: NB 0197
No.56: Nebulizers: Adult Mask(SEBS) (NEB-MSLS-E)	Class IIa	N/A (No.39)	HD 2102042-1: NB 0197
No.57: Nebulizers: NEB-TSC-L10 (NEB-TSC-L10E)	Class IIa	N/A (No.47)	HD 2102042-1: NB 0197
No.58: Nebulizers: NEB-TP-82 (NEB-TP-82E)	Class IIa	N/A (No.77)	HD 2102042-1: NB 0197
No.59: Nebulizers: NEB-TP-L10 (NEB-TP-L10E)	Class IIa	N/A (No.46)	HD 2102042-1: NB 0197
No.60: Nebulizers: NEB-TP-L20 (NEB-TP-L20E)	Class IIa	N/A (No.98)	HD 2102042-1: NB 0197
No.61: Nebulizers: U22-1-E	Class IIa	N/A (No.120)	HD 2102042-1: NB 0197
No.62: Nebulizers: NEB-NSET1-90E	Class IIa	N/A (No.92)	HD 2102042-1: NB 0197
No.63: Nebulizers: Mesh Cap	Class IIa	N/A (No.118)	HD 2102042-1: NB 0197
No.64: Nebulizers: NEB-NSET3-28 (NEB-NSET3-28E)	Class IIa	N/A (No.4)	HD 2102042-1: NB 0197
No.65: Nebulizers: NEB-TPC-L20 (NEB-TPC-L20E)	Class IIa	N/A (No.5)	HD 2102042-1: NB 0197
No.66: Nebulizers: NEB-AFS-78E	Class IIa	N/A (No.126)	HD 2102042-1: NB 0197

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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
No.67: Nebulizers: NEB-BFC-78E	Class IIa	N/A (No.127)	HD 2102042-1: NB 0197
No.68: Nebulizers: NEB-HS-L15E	Class IIa	N/A (No.128)	HD 2102042-1: NB 0197
No.69: Nebulizers: NEB-HS-L70E	Class IIa	N/A (No.129)	HD 2102042-1: NB 0197
No.70: Nebulizers: NEB-LMCC-78E	Class IIa	N/A (No.130)	HD 2102042-1: NB 0197
No.71: Nebulizers: NEB-MPSS-78E	Class IIa	N/A (No.131)	HD 2102042-1: NB 0197
No.72: Nebulizers: NEB-MSILS-78E	Class IIa	N/A (No.132)	HD 2102042-1: NB 0197
No.73: Nebulizers: NEB-MSISS-78E	Class IIa	N/A (No.133)	HD 2102042-1: NB 0197
No.74: Nebulizers: NEB-NZU-78E	Class IIa	N/A (No.134)	HD 2102042-1: NB 0197
No.75: Nebulizers: NEB-SP-78E	Class IIa	N/A (No.135)	HD 2102042-1: NB 0197
No.76: Nebulizers: NEB-MC-10E	Class IIa	N/A (No.138)	HD 2102042-1: NB 0197
No.77: Nebulizers: NEB-BTL-10E	Class IIa	N/A (No.137)	HD 2102042-1: NB 0197
No.78: Nebulizers: NEB-MSA-10E	Class IIa	N/A (No.139)	HD 2102042-1: NB 0197
No.79: Nebulizers: NEB-NSET4-83AP	Class IIa	N/A (No.83)	HD 2102042-1: NB 0197
No.80: Nebulizers: NEB-NSET4-90 (NEB-NSET4-90AP)	Class IIa	N/A (No.94)	HD 2102042-1: NB 0197
No.81: Nebulizers: NEB-NSET5-83AP	Class IIa	N/A (No.84)	HD 2102042-1: NB 0197
No.82: Nebulizers: NEB-NSET5-90 (NEB-NSET5-90AP)	Class IIa	N/A (No.95)	HD 2102042-1: NB 0197
No.83: Nebulizers: NEB-NSET6-90 (NEB-NSET6-90AP)	Class IIa	N/A (No.96)	HD 2102042-1: NB 0197
No.84: Nebulizers: NEB-MSLP-AP	Class IIa	N/A (No.36)	HD 2102042-1: NB 0197
No.85: Nebulizers: NEB-MSMP-AP	Class IIa	N/A (No.38)	HD 2102042-1: NB 0197
No.86: Nebulizers: Nebulisation Set (U17-5-E)	Class IIa	N/A (No.107)	HD 2102042-1: NB 0197
No.87: Nebulizers: NEB-MP-AP	Class IIa	N/A (No.41)	HD 2102042-1: NB 0197
No.88: Nebulizers: NEB-NP-AP	Class IIa	N/A (No.43)	HD 2102042-1: NB 0197
No.89: Nebulizers: NEB-TP-L10AP	Class IIa	N/A (No.45)	HD 2102042-1: NB 0197
No.90: Nebulizers: NEB-NK-11AP	Class IIa	N/A (No.21)	HD 2102042-1: NB 0197
No.91: Nebulizers: NEB-NSET4-11AP	Class IIa	N/A (No.22)	HD 2102042-1: NB 0197
No.92: Nebulizers: NEB-NSET5-11AP	Class IIa	N/A (No.23)	HD 2102042-1: NB 0197
No.93: Nebulizers: NEB-TSC-L20AP	Class IIa	N/A (No.48)	HD 2102042-1: NB 0197
No.94: Nebulizers: NEB-ASKIT-16AP	Class IIa	N/A (No.25)	HD 2102042-1: NB 0197
No.95: Clinical Electronic Thermometers: Flex Temp Smart (MC-343F-E)	Class IIa	N/A (No.478)	HD 2102042-1: NB 0197
No.96: Clinical Electronic Thermometers: MC-246	Class IIa	N/A (No.464)	HD 2102042-1: NB 0197

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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
No.97: Clinical Electronic Thermometers: MC-341	Class IIa	N/A (No.473)	HD 2102042-1: NB 0197
No.98: Clinical Electronic Thermometers: MC-343F	Class IIa	N/A (No.477)	HD 2102042-1: NB 0197
No.99: Electronic Sphygmomanometers: M300 (HEM-7121-D)	Class IIa	N/A (No.287)	HD 2102042-1: NB 0197
No.100: Electronic Sphygmomanometers: M2 (HEM-7121-E)	Class IIa	N/A (No.288)	HD 2102042-1: NB 0197
No.101: Electronic Sphygmomanometers: HBP-1120 (HBP-1120-E)	Class IIa	N/A (No.451)	HD 2102042-1: NB 0197
No.102: Electronic Sphygmomanometers: HBP-1320 (HBP-1320-E)	Class IIa	N/A (No.459)	HD 2102042-1: NB 0197
No.103: Electronic Sphygmomanometers: HEM-907 (HEM-907-E7)	Class IIa	N/A (No.443)	HD 2102042-1: NB 0197
No.104: Electronic Sphygmomanometers: HEM-7120	Class IIa	N/A (No.280)	HD 2102042-1: NB 0197
No.105: Electronic Sphygmomanometers: HEM-7121	Class IIa	N/A (No.284)	HD 2102042-1: NB 0197
No.106: Electronic Sphygmomanometers: BP100 (HEM-7122-AU)	Class IIa	N/A (No.300)	HD 2102042-1: NB 0197
No.107: Electronic Sphygmomanometers: HEM-8712	Class IIa	N/A (No.434)	HD 2102042-1: NB 0197
No.108: Electronic Sphygmomanometers: HEM-907	Class IIa	N/A (No.444)	HD 2102042-1: NB 0197
No.109: Electronic Sphygmomanometers: HEM-7600T	Class IIa	N/A (No.422)	HD 2102042-1: NB 0197
No.110: Electronic Sphygmomanometers: HEM-7124	Class IIa	N/A (No.304)	HD 2102042-1: NB 0197
No.111: Electronic Sphygmomanometers: RS1 (HEM-6160-E)	Class IIa	N/A (No.200)	HD 2102042-1: NB 0197
No.112: Electronic Sphygmomanometers: RS2 (HEM-6161-E)	Class IIa	N/A (No.203)	HD 2102042-1: NB 0197
No.113: Electronic Sphygmomanometers: RS4 (HEM-6181-E)	Class IIa	N/A (No.209)	HD 2102042-1: NB 0197
No.114: Electronic Sphygmomanometers: RS7 Intelli IT (HEM-6232T-E)	Class IIa	N/A (No.220)	HD 2102042-1: NB 0197
No.115: Electronic Sphygmomanometers: RS2 (HEM-6161-D)	Class IIa	N/A (No.202)	HD 2102042-1: NB 0197
No.116: Electronic Sphygmomanometers: RS4 (HEM-6181-D)	Class IIa	N/A (No.208)	HD 2102042-1: NB 0197
No.117: Electronic Sphygmomanometers: RS7 Intelli IT (HEM-6232T-D)	Class IIa	N/A (No.219)	HD 2102042-1: NB 0197

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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
No.118: Electronic Sphygmomanometers: HEM-6161	Class IIa	N/A (No.201)	HD 2102042-1: NB 0197
No.119: Electronic Sphygmomanometers: HEM-6181	Class IIa	N/A (No.207)	HD 2102042-1: NB 0197
No.120: Electronic Sphygmomanometers: HEM-6232T	Class IIa	N/A (No.218)	HD 2102042-1: NB 0197
No.121: Electronic Sphygmomanometers: HBP-1120 (HBP-1120-E)	Class IIa	N/A (No.453)	HD 2102042-1: NB 0197
No.122: Electronic Sphygmomanometers: HBP-1320 (HBP-1320-E)	Class IIa	N/A (No.460)	HD 2102042-1: NB 0197
No.123: Electronic Sphygmomanometers: RS3 Intelli IT (HEM-6161T-E)	Class IIa	N/A (No.205)	HD 2102042-1: NB 0197
No.124: Electronic Sphygmomanometers: RS3 Intelli IT (HEM-6161T-D)	Class IIa	N/A (No.204)	HD 2102042-1: NB 0197
No.125: Electronic Sphygmomanometers: HEM-7121J	Class IIa	N/A (No.296)	HD 2102042-1: NB 0197
No.126: Electronic Sphygmomanometers: HeartGuide (HEM-6411T-MAE)	Class IIa	N/A (No.229)	HD 2102042-1: NB 0197
No.127: Electronic Sphygmomanometers: M2 Basic (HEM-7121J-E)	Class IIa	N/A (No.293)	HD 2102042-1: NB 0197
No.128: Electronic Sphygmomanometers: M1 Basic (HEM-7121J-AF)	Class IIa	N/A (No.291)	HD 2102042-1: NB 0197
No.129: Electronic Sphygmomanometers: M1 Basic (HEM-7121J-LAF)	Class IIa	N/A (No.297)	HD 2102042-1: NB 0197
No.130: Electronic Sphygmomanometers: HEM-7157T	Class IIa	N/A (No.347)	HD 2102042-1: NB 0197
No.131: Electronic Sphygmomanometers: NightView (HEM-9601T-E3)	Class IIa	N/A (No.441)	HD 2102042-1: NB 0197
No.132: Electronic Sphygmomanometers: HBP-9030	Class IIa	N/A (No.461)	HD 2102042-1: NB 0197
No.133: Electronic Sphygmomanometers: X2 Basic (HEM-7121J-EO)	Class IIa	N/A (No.294)	HD 2102042-1: NB 0197
No.134: Electronic Sphygmomanometers: HEM-7156	Class IIa	N/A (No.344)	HD 2102042-1: NB 0197
No.135: Electronic Sphygmomanometers: HEM-7156-A	Class IIa	N/A (No.343)	HD 2102042-1: NB 0197
No.136: Electronic Sphygmomanometers: M6 Comfort (HEM-7360-E)	Class IIa	N/A (No.415)	HD 2102042-1: NB 0197
No.137: Electronic Sphygmomanometers: X6 Comfort (HEM-7360-EO)	Class IIa	N/A (No.416)	HD 2102042-1: NB 0197
No.138: Electronic Sphygmomanometers: M7 Intelli IT (HEM-7361T-EBK)	Class IIa	N/A (No.420)	HD 2102042-1: NB 0197

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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
No.139: Electronic Sphygmomanometers: X7 Smart (HEM-7361T-ESL)	Class IIa	N/A (No.421)	HD 2102042-1: NB 0197
No.140: Electronic Sphygmomanometers: M500 Intelli IT (HEM-7361T-D)	Class IIa	N/A (No.419)	HD 2102042-1: NB 0197
No.141: Electronic Sphygmomanometers: HEM-7361T	Class IIa	N/A (No.418)	HD 2102042-1: NB 0197
No.142: Electronic Sphygmomanometers: M3 (HEM-7154-E)	Class IIa	N/A (No.333)	HD 2102042-1: NB 0197
No.143: Electronic Sphygmomanometers: M3 Comfort (HEM-7155-E)	Class IIa	N/A (No.336)	HD 2102042-1: NB 0197
No.144: Electronic Sphygmomanometers: X3 Comfort (HEM-7155-EO)	Class IIa	N/A (No.337)	HD 2102042-1: NB 0197
No.145: Electronic Sphygmomanometers: M400 Comfort (HEM-7155-D)	Class IIa	N/A (No. 335)	HD 2102042-1: NB 0197
No.146: Electronic Sphygmomanometers: M4 Intelli IT (HEM-7155T-EBK)	Class IIa	N/A (No.341)	HD 2102042-1: NB 0197
No.147: Electronic Sphygmomanometers: X4 Smart (HEM-7155T-ESL)	Class IIa	N/A (No. 342)	HD 2102042-1: NB 0197
No.148: Electronic Sphygmomanometers: M400 Intelli IT (HEM-7155T-D)	Class IIa	N/A (No.340)	HD 2102042-1: NB 0197
No.149: Electronic Sphygmomanometers: HBP-1120	Class IIa	N/A (No.452)	HD 2102042-1: NB 0197
No.150: Electronic Sphygmomanometers: HBP-1320	Class IIa	N/A (No.457)	HD 2102042-1: NB 0197
No.151: Electronic Sphygmomanometers: HBP-1320	Class IIa	N/A (No.458)	HD 2102042-1: NB 0197
No.152: Electronic Sphygmomanometers: HEM-7155T	Class IIa	N/A (No.339)	HD 2102042-1: NB 0197
No.153: Electronic Sphygmomanometers: HEM-7156T	Class IIa	N/A (No.346)	HD 2102042-1: NB 0197
No.154: Electronic Sphygmomanometers: HEM-7156T-A	Class IIa	N/A (No.345)	HD 2102042-1: NB 0197
No.155: Electronic Sphygmomanometers: HEM-7140T1	Class IIa	N/A (No.327)	HD 2102042-1: NB 0197
No.156: Electronic Sphygmomanometers: HEM-7141T1	Class IIa	N/A (No.328)	HD 2102042-1: NB 0197
No.157: Electronic Sphygmomanometers: HEM-7142T1	Class IIa	N/A (No.329)	HD 2102042-1: NB 0197
No.158: Electronic Sphygmomanometers: HEM-7143T1	Class IIa	N/A (No.330)	HD 2102042-1: NB 0197
No.159: Electronic Sphygmomanometers: HEM-7144T1	Class IIa	N/A (No.331)	HD 2102042-1: NB 0197

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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
No.160: Electronic Sphygmomanometers: M300 (HEM-7121J-D)	Class IIa	N/A (No.295)	HD 2102042-1: NB 0197
No.161: Ear Thermometers: Gentle Temp 521 (MC-521-E)	Class IIa	N/A (No.484)	HD 2102042-1: NB 0197
No.162: Ear Thermometers: MC-522	Class IIa	N/A (No.486)	HD 2102042-1: NB 0197
No.163: Infrared Forehead Thermometers: MC-720	Class IIa	N/A (No.490)	HD 2102042-1: NB 0197
No.164: Electroanalgesic Transcutaneous Stimulators: E3 Intense (HV-F021-ESL)	Class IIa	N/A (No.143)	HD 2102042-1: NB 0197
No.165: Electroanalgesic Transcutaneous Stimulators: E3 Intense (HV-F021-EW)	Class IIa	N/A (No.144)	HD 2102042-1: NB 0197
No.166: Electroanalgesic Transcutaneous Stimulators: HV-F021	Class IIa	N/A (No.142)	HD 2102042-1: NB 0197
No.167: Electroanalgesic Transcutaneous Stimulators: HV-F013	Class IIa	N/A (No.140)	HD 2102042-1: NB 0197
No.168: Electroanalgesic Transcutaneous Stimulators: PocketTens (HV-F013-E)	Class IIa	N/A (No.141)	HD 2102042-1: NB 0197
No.169: Electroanalgesic Transcutaneous Stimulators: HeatTens (HV-F311-UK)	Class IIa	N/A (No.150)	HD 2102042-1: NB 0197
No.205: Nebulizers: NE-C28 Plus (NE-C28P-RU)	Class IIa	N/A (No.10)	HD 2102042-1: NB 0197
No. 206: Nebulizers: NE-C24 (NE-C801S-RU)	Class IIa	N/A (No.66)	HD 2102042-1: NB 0197
No. 207: Nebulizers: NE-C24 Kids (NE-C801S-KDRU)	Class IIa	N/A (No.61)	HD 2102042-1: NB 0197
No.208: Application Program Software for Electrocardiogram: OMRON connect	Class IIa	N/A (No.153)	HD 2102042-1: NB 0197
No.210: Electronic Sphygmomanometers: RS2 Intelli IT (HEM-6161T-RU)	Class IIa	N/A (No.206)	HD 2102042-1: NB 0197
No.211: Electronic Sphygmomanometers: RS7 Intelli IT (HEM-6232T-RU)	Class IIa	N/A (No.221)	HD 2102042-1: NB 0197
No.212: Electronic Sphygmomanometers: M3 Expert (ALRU)	Class IIa	N/A (No.332)	HD 2102042-1: NB 0197
No.213: Electronic Sphygmomanometers: M3 Comfort (ALRU)	Class IIa	N/A (No.334)	HD 2102042-1: NB 0197
No.214: Electronic Sphygmomanometers: M4 Intelli IT (ALRU)	Class IIa	N/A (No.338)	HD 2102042-1: NB 0197
No.215: Electronic Sphygmomanometers: M2 Basic (HEM-7121-RU)	Class IIa	N/A (No.290)	HD 2102042-1: NB 0197
No.216: Electronic Sphygmomanometers: M2 Basic (HEM-7121-ARU)	Class IIa	N/A (No.285)	HD 2102042-1: NB 0197
No.217: Electronic Sphygmomanometers: M2 Basic (HEM-7121-ALRU)	Class IIa	N/A (No.283)	HD 2102042-1: NB 0197
No.219: Electronic Sphygmomanometers: RS1 (HEM-6120-RU)	Class IIa	N/A (No.186)	HD 2102042-1: NB 0197

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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
No.220: Electronic Sphygmomanometers: RS2 (HEM-6121-RU)	Class IIa	N/A (No.191)	HD 2102042-1: NB 0197
No.221: Electronic Sphygmomanometers: M2 Comfort (ALRU)	Class IIa	N/A (No.302)	HD 2102042-1: NB 0197
No.222: Electronic Sphygmomanometers: M2 Eco (RU)	Class IIa	N/A (No.308)	HD 2102042-1: NB 0197
No.223: Electronic Sphygmomanometers: M2 Eco (ARU)	Class IIa	N/A (No.305)	HD 2102042-1: NB 0197
No.224: Electronic Sphygmomanometers: M2 Plus (ARU)	Class IIa	N/A (No.307)	HD 2102042-1: NB 0197
No.225: Electronic Sphygmomanometers: M1 Basic (RU)	Class IIa	N/A (No.298)	HD 2102042-1: NB 0197
No.226: Electronic Sphygmomanometers: M1 Basic (ARU)	Class IIa	N/A (No.292)	HD 2102042-1: NB 0197
No.227: Clinical Electronic Thermometers: Eco Temp Basic (MC-246-RU)	Class IIa	N/A (No.467)	HD 2102042-1: NB 0197
No.228: Clinical Electronic Thermometers: Eco Temp Smart (MC-341-RU)	Class IIa	N/A (No.476)	HD 2102042-1: NB 0197
No.229: Clinical Electronic Thermometers: Flex Temp Smart (MC-343F-RU)	Class IIa	N/A (No.480)	HD 2102042-1: NB 0197
No.236: Clinical Electronic Thermometers: MC-245	Class IIa	N/A (No.463)	HD 2102042-1: NB 0197
No.237: Nebulizers: NE-C28P (NE-C28P-E)	Class IIa	N/A (No.8)	HD 2102042-1: NB 0197
No.238: Nebulizers: NE-C28P (NE-C28P-D)	Class IIa	N/A (No.7)	HD 2102042-1: NB 0197
No.239: Nebulizers: NE-C28P (NE-C28P-UK)	Class IIa	N/A (No.11)	HD 2102042-1: NB 0197
No.240: Nebulizers: NE-C20 (NE-C802-RU)	Class IIa	N/A (No.79)	HD 2102042-1: NB 0197
No.241: Nebulizers: NEB-NKKD1-81 (NEB-NKKD1-81E)	Class IIa	N/A (No.58)	HD 2102042-1: NB 0197
No.242: Nebulizers: NEB-NKKD2-81 (NEB-NKKD2-81E)	Class IIa	N/A (No.59)	HD 2102042-1: NB 0197
No.243: Nebulizers: NEB-NAF-81AP	Class IIa	N/A (No.34)	HD 2102042-1: NB 0197
No.244: Nebulizers: NE-C801KD (NE-C801S-KDD)	Class IIa	N/A (No.56)	HD 2102042-1: NB 0197
No.245: Nebulizers: Inhalation hose M	Class IIa	N/A (No.112)	HD 2102042-1: NB 0197
No.246: Nebulizers: Medication Container	Class IIa	N/A (No.119)	HD 2102042-1: NB 0197
No.247: Electronic Sphygmomanometers: HEM-7121	Class IIa	N/A (No.286)	HD 2102042-1: NB 0197
No.248: Electronic Sphygmomanometers: HEM-7130	Class IIa	N/A (No.309)	HD 2102042-1: NB 0197
No.249: Electronic Sphygmomanometers: HEM-7130	Class IIa	N/A (No.310)	HD 2102042-1: NB 0197
No.250: Electronic Sphygmomanometers:	Class IIa	N/A (No.312)	HD 2102042-1: NB 0197

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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
HEM-7130-L			
No.251: Electronic Sphygmomanometers: HEM-7130	Class IIa	N/A (No.314)	HD 2102042-1: NB 0197
No.252: Electronic Sphygmomanometers: HEM-7320	Class IIa	N/A (No.403)	HD 2102042-1: NB 0197
No.253: Electronic Sphygmomanometers: M2 Basic (HEM-7120-E)	Class IIa	N/A (No.281)	HD 2102042-1: NB 0197
No.254: Electronic Sphygmomanometers: M2 Eco (HEM-7120-AF)	Class IIa	N/A (No.279)	HD 2102042-1: NB 0197
No.255: Electronic Sphygmomanometers: M3 (HEM-7131-E)	Class IIa	N/A (No.318)	HD 2102042-1: NB 0197
No.256: Electronic Sphygmomanometers: M400 (HEM-7131-D)	Class IIa	N/A (No.317)	HD 2102042-1: NB 0197
No.257: Electronic Sphygmomanometers: M6 Comfort (HEM-7321-E)	Class IIa	N/A (No.406)	HD 2102042-1: NB 0197
No.258: Electronic Sphygmomanometers: M500 (HEM-7321-D)	Class IIa	N/A (No.405)	HD 2102042-1: NB 0197
No.259: Nebulizers: NE-C801 (NE-C801S-D)	Class IIa	N/A (No.30)	HD 2102042-1: NB 0197
No.260: Nebulizers: Mouthpiece set	Class IIa	N/A (No.108)	HD 2102042-1: NB 0197
No.261: Ear Thermometers: Gentle Temp 522 PRO (MC-522-E)	Class IIa	N/A (No.485)	HD 2102042-1: NB 0197
No.262: Electronic Sphygmomanometers: MIT5s Connect (HEM-7280T-E)	Class IIa	N/A (No.399)	HD 2102042-1: NB 0197
No.263: Electronic Sphygmomanometers: MIT3 (HEM-7270-E)	Class IIa	N/A (No.395)	HD 2102042-1: NB 0197
No.264: Nebulizers: NE-C803	Class IIa	N/A (No.88)	HD 2102042-1: NB 0197
No.265: Electronic Sphygmomanometers: M3 Family (HEM-7133-ALRU)	Class IIa	N/A (No.323)	HD 2102042-1: NB 0197
No.266: Electronic Sphygmomanometers: M3 Expert (HEM-7132-ALRU)	Class IIa	N/A (No.321)	HD 2102042-1: NB 0197
No.267: Electronic Sphygmomanometers: M3 Eco (HEM-7131-ARU)	Class IIa	N/A (No.316)	HD 2102042-1: NB 0197
No.268: Electronic Sphygmomanometers: M2 Classic (HEM-7122-LRU)	Class IIa	N/A (No.301)	HD 2102042-1: NB 0197
No.269: Electronic Sphygmomanometers: M3 Comfort (HEM-7134-E)	Class IIa	N/A (No.325)	HD 2102042-1: NB 0197
No.270: Electronic Sphygmomanometers: M400 (HEM-7134-D)	Class IIa	N/A (No.326)	HD 2102042-1: NB 0197
No.271: Electronic Sphygmomanometers: M3 Comfort (HEM-7134-ALRU)	Class IIa	N/A (No.324)	HD 2102042-1: NB 0197
No.272: Electronic Sphygmomanometers: BOOTS BLOOD PRESSURE MONITOR UPPER ARM (66-13-896)	Class IIa	N/A (No.445)	HD 2102042-1: NB 0197

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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
No.273: Electronic Sphygmomanometers: JPN500	Class IIa	N/A (No.303)	HD 2102042-1: NB 0197
No.274: Electronic Sphygmomanometers: JPN600	Class IIa	N/A (No.315)	HD 2102042-1: NB 0197
No.275: Electronic Sphygmomanometers: HEM-7280T	Class IIa	N/A (No.397)	HD 2102042-1: NB 0197
No.276: Electronic Sphygmomanometers: HEM-9210T (HEM-9210T-E)	Class IIa	N/A (No.440)	HD 2102042-1: NB 0197
No.277: Electronic Sphygmomanometers: HEM-9210T	Class IIa	N/A (No.439)	HD 2102042-1: NB 0197
No.278: Electronic Sphygmomanometers: 717 (HEM-8712-CM)	Class IIa	N/A (No.435)	HD 2102042-1: NB 0197
No.279: Electronic Sphygmomanometers: 711 (HEM-8712-CM2)	Class IIa	N/A (No.436)	HD 2102042-1: NB 0197
No.280: Nebulizers: NE-C28P (NE-C28P-KSA)	Class IIa	N/A (No.9)	HD 2102042-1: NB 0197
No.281: Electronic Sphygmomanometers: Boots BPM Wrist 82-01-749	Class IIa	N/A (No.432)	HD 2102042-1: NB 0197
No.282: Electronic Sphygmomanometers: RS3 (HEM-6130-RU)	Class IIa	N/A (No.194)	HD 2102042-1: NB 0197
No.283: Clinical Electronic Thermometers: Eco Temp Intelli IT (MC-280B)	Class IIa	N/A (No.472)	HD 2102042-1: NB 0197
No.284: Nebulizers: NE-C801	Class IIa	N/A (No.65)	HD 2102042-1: NB 0197
No.285: Clinical Electronic Thermometers: MC-685-HP	Class IIa	N/A (No.488)	HD 2102042-1: NB 0197
No.286: Electronic Sphygmomanometers: BOOTS BLOOD PRESSURE MONITOR UPPER ARM (66-13-918)	Class IIa	N/A (No.446)	HD 2102042-1: NB 0197
No.287: Electronic Sphygmomanometers: Boots Advanced Blood Pressure Monitor Upper Arm (66-13-926)	Class IIa	N/A (No.447)	HD 2102042-1: NB 0197
No.288: Electronic Sphygmomanometers: M7 Intelli IT (ALRU)	Class IIa	N/A (No.417)	HD 2102042-1: NB 0197
No.289: Electronic Sphygmomanometers: M2 Plus (ALRU)	Class IIa	N/A (No.306)	HD 2102042-1: NB 0197
No. 290: Electroanalgesic Transcutaneous Stimulators: Avail (HV-F601T-E)	Class IIa	N/A (No.151)	HD 2102042-1: NB 0197
No.13: Body Composition Analyzers: VIVA (HBF-222T-EBK)	Class Im	N/A (No.7)	DD 60137913 0001: NB 0197
No.171: Body Composition Analyzers: BF212 (HBF-212-EW)	Class Im	N/A (No.4)	DD 60137913 0001: NB 0197
No.172: Body Composition Analyzers: BF214 (HBF-214-EBW)	Class Im	N/A (No.5)	DD 60137913 0001: NB 0197
No.173: Body Composition Analyzers: BF508 (HBF-508-E)	Class Im	N/A (No.10)	DD 60137913 0001: NB 0197
No.174: Body Composition Analyzers: BF511 (HBF-511B-E)	Class Im	N/A (No.12)	DD 60137913 0001: NB 0197

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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
No.175: Body Composition Analyzers: BF511 (HBF-511T-E)	Class Im	N/A (No.13)	DD 60137913 0001: NB 0197
No.176: Body Composition Analyzers: HBF-222T	Class Im	N/A (No.6)	DD 60137913 0001: NB 0197

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/02/22	OHQ_CL607_2024-02-22	Initial issue