OLYMPUS

# EU-DECLARATION OF CONFORMITY

| | |
|---|---|
| **1. Manufacturer** | OLYMPUS MEDICAL SYSTEMS CORP. |
| | 2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan |
| **Single Registration-No.** | JP-MF-000008016 |
| **2. Article(REF)No. / Article Name** | Please refer to Attachment 1 |
| **3. Product designation** | Please refer to Attachment 1 |
| **4. Serial or Lot No. range** | Please refer to Attachment 1 |
| **5. Product classification** | Please refer to Attachment 1 |
| **6. Authorized representatives in EU** | |
| **Name** | Olympus Europa SE & Co. KG |
| **Address** | Wendenstrasse 20, 20097 Hamburg, Germany |
| **Single Registration-No.** | DE-AR-000006774 |

**7. Declaration**

This declaration was made in sole responsibility of the manufacturer.
The stated product complies with the requirements of following European Directives and Regulations.

| | | |
|---|---|---|
| The declarations is based on: | (EU)2017/745 | Annex II,III |
| | 2011/65/EU, (EU) 2015/863 | |

**Place, Date:** Tokyo, 2022/8/29

**Signature:**

Product Quality Assurance
Medical Quality Assurance and Regulatory Affairs

# ATTACHMENT 1

OLYMPUS

✦The EU-Declaration of Conformity is valid for the following articles:

| Product designation | Article(REF)No. / Article Name | Serial or Lot No. range | Remark | UDI-DI |
|---|---|---|---|---|
| VISERA ELITE III VIDEO SYSTEM CENTER OTV-S700 | OLYMPUS OTV-S700 | From 7200168 to | - | 04953170433337 |

| GMDN | EMDN | Basic UDI-DI | Classification* | Rule* |
|---|---|---|---|---|
| 18034 | Z120204 | 495317000099C4 | Class I | 13 |

* According to Annex VIII for (EU) 2017/745, Annex IX for 93/42 /EEC

✦Applied Standards [RoHS,RED,LVD,EMC]

| |
|---|
| [RoHS] EN IEC 63000 : 2018 |

Refer to the GSPR Checklist for above mentioned product. [MDR]

✦Intended purpose (MDR only) / Product Description:

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|---|
| This video system center is intended to be used with OLYMPUS camera heads, endoscopes, monitors, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis, treatment, and video observation. |

✦Serial or Lot No.

| Directive/Regulation | Re-issued DoC-Serial or Lot No. range Starting from | Ended at | New DoC-Serial or Lot No. range Starting from |
|---|---|---|---|
| (EU)2017/745 | - | - | 7200168 |
| 2011/65/EU, (EU) 2015/863 | - | - | - |

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# ES PROHLÁŠENÍ O SHODĚ

| | | |
|---|---|---|
| 1. | **Výrobce** | OLYMPUS MEDICAL SYSTEMS CORP.<br>2951 Ishikawa-cho, Hachioji-shi, Tokio 192-8507,<br>Japonsko |
| | **Jediné registrační číslo (SRN)** | JP-MF-000008016 |
| 2. | **Referenční číslo /<br>název zdravotnického prostředku** | viz příloha č. 1 |
| 3. | **Označení zdravotnického prostředku** | viz příloha č. 1 |
| 4. | **Výrobní číslo nebo číslo šarže (rozpětí)** | viz příloha č. 1 |
| 5. | **Klasifikace zdravotnického prostředku** | viz příloha č. 1 |
| 6. | **Zplnomocněný zástupce pro EU** | |
| | **Obchodní firma:** | Olympus Europa SE & Co. KG |
| | **Adresa:** | Wendenstrasse 20, 20097 Hamburg, Německo |
| | **Jediné registrační číslo (SRN)** | DE-AR-000006774 |
| 7. | **Prohlášení** | |

Prohlášení činí na vlastní výhradní odpovědnost výrobce.
Uvedený zdravotnický prostředek je ve shodě s požadavky následujících evropských směrnic a nařízení.

| | |
|---|---|
| Základem prohlášení je: | nařízení (EU) 2017/745, příloha II, III<br>směrnice 2011/65/EU, nařízení (EU) 2015/863 |

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| | |
|---|---|
| **Místo, datum:** | Tokio, 29.08.2022 |
| **Podpis:** | [podpis]<br>ředitel<br>oddělení zabezpečování jakosti<br>odbor medicínské jakosti a regulačních záležitostí |

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# PŘÍLOHA č. 1

♦ ES prohlášení o shodě platí pro následující zdravotnické prostředky („ZP"):

| Označení ZP | ZP č. (REF) Název ZP | Výrobní č. nebo č. šarže (rozpětí) | Poznámka | UDI-DI | Kód GMDN | Kód EMDN | Základní UDI-DI | Klasifikace* | Pravidlo* |
|---|---|---|---|---|---|---|---|---|---|
| videosystémové centrum VISERA ELITE III OTV-S700 | OLYMPUS OTV-S700 | od 7200168 do | — | 04953170433337 | 18034 | Z120204 | 495317000099C4 | třída I | 13 |

* Podle Přílohy VIII směrnice (EU) 2017/745

♦ Použité normy (RoHS, RED, LVD, EMC)

| | |
|---|---|
| [RoHS] | EN IEC 63000:2018 |

viz kontrolní seznam podstatných požadavků pro výše uvedený zdravotnický prostředek (podle směrnice o zdravotnických prostředcích)

♦ Zamýšlený účel (pouze podle směrnice o zdravotnických prostředcích) / popis ZP:

Videosystémové centrum je určeno k použití s kamerovými hlavami, endoskopy, monitory, endoterapeutickým příslušenstvím a dalším pomocným vybavením OLYMPUS k endoskopické diagnostice, léčbě a videomonitorování.

♦ Výrobní číslo nebo číslo šarže

| Směrnice / nařízení | Pořadové č. opakovaně vydaného dokumentu nebo č. šarže (rozpětí) od | do | Pořadové č. nově vydaného dokumentu nebo č. šarže (rozpětí) od |
|---|---|---|---|
| nařízení (EU) 2017/745 | – | – | 7200168 |
| směrnice 2011/65/EU, nařízení (EU) 2015/863 | – | – | – |

**Business Stream Products**
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Olympus Winter & Ibe GmbH
Kuehnstr. 61
22045 Hamburg
Germany

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date April 24, 2024

**Notified Body Confirmation Letter**
Reference: OSTE_MDR Application 2024-04-16; order # 1159799

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:

Olympus Winter & Ibe GmbH
Kuehnstr. 61
22045 Hamburg
Germany
SRN Number (if available): DE-MF-000006729

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. 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 May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either 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 March 20, 2023 for the relevant devices.

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety

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:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 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)
- 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
- December 31, 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

Certification body

**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 |
|---|---|---|---|
| **40427611102852** | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| **40427611105657** | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| **40427611105759** | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| **40427611106252** | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| **40427611106354** | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| **40427611102954** | IIa | N/A | HD 60151129 0001 #0197 |
| **40427611107459** | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| **40427611106456** | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| **40427611106558** | IIb non-implantable | N/A | HD 60151129 0001 #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/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| 4042761110024G | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 4042761110034J | IIa | N/A | HD 60151129 0001 #0197 |
| 40427611112755 | IIa | A22091A<br>A42091A | HD 60151129 0001 #0197 |
| 40427611112959 | IIa | N/A | HD 60151129 0001 #0197 |
| 4042761111304S | IIa | N/A | HD 60151129 0001 #0197 |
| 4042761111314U | IIa | N/A | HD 60151129 0001 #0197 |
| 4042761111324W | IIa | N/A | HD 60151129 0001 #0197 |
| 4042761111334Y | IIa | N/A | HD 60151129 0001 #0197 |
| 40427611113452 | IIa | N/A | HD 60151129 0001 #0197 |
| 40427611113554 | IIa | N/A | HD 60151129 0001 #0197 |
| 40427611113656 | IIa | N/A | HD 60151129 0001 #0197 |
| 4042761111395C | IIa | N/A | HD 60151129 0001 #0197 |
| 4042761111404V | IIa | N/A | HD 60151129 0001 #0197 |
| 4042761111414X | IIa | A37025A | HD 60151129 0001 #0197 |
| 4042761111424Z | IIa | A20919A<br>A20918A | HD 60151129 0001 #0197 |
| 40427611114557 | IIa | A4760<br>A47610A<br>A4761<br>A4770<br>A4771<br>A4772<br>A4773<br>A4775<br>A4776 | HD 60151129 0001 #0197 |
| 40427611114659 | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 4042761111475B | Is | N/A | HD 60151129 0001 #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/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| **4042761111485D** | IIa | A37022A<br>A37025A<br>WA33038A<br>WA33037A | HD 60151129 0001 #0197 |
| **4042761111504Y** | IIa | N/A | HD 60151129 0001 #0197 |
| **40427611115152** | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| **40427611115254** | IIb non-implantable | A6294<br>A6292<br>A6299<br>A6293 | HD 60151129 0001 #0197 |
| **40427611115356** | IIb non-implantable | WA90004W<br>WA90004C<br>WA90004J | HD 60151129 0001 #0197 |
| **4042761111575E** | Is | N/A | HD 60151129 0001 #0197 |
| **4042761111585G** | IIa | O0102.1 | HD 60151129 0001 #0197 |
| **40427611116053** | IIa | N/A | HD 60151129 0001 #0197 |
| **40427611116257** | IIa | WA22810A<br>WA22850A | HD 60151129 0001 #0197 |
| **40427611116359** | IIa | A70950A<br>A70970A<br>WA70990A<br>WA70992A<br>A70951A<br>A70971A<br>WA70991A<br>WA70993A | HD 60151129 0001 #0197 |
| **4042761111645B** | IIa | A70951A<br>A70950A<br>A70971A<br>A70970A<br>WA70991A<br>WA70990A<br>WA70993A<br>WA70992A | HD 60151129 0001 #0197 |
| **4042761111675H** | Ir | N/A | HD 60151129 0001 #0197 |
| **4042761111685K** | Ir | N/A | HD 60151129 0001 #0197 |
| **4042761111695M** | IIb non-implantable | N/A | HD 60151129 0001 #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/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| 40427611117158 | Ir | N/A | HD 60151129 0001 #0197 |
| 4042761111765J | IIa | A3551<br>A3552 | HD 60151129 0001 #0197 |
| 4042761111775L | Ir | N/A | HD 60151129 0001 #0197 |
| 4042761111775L | IIa | N/A | HD 60151129 0001 #0197 |
| 40427681108589 | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 4042768110868B | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 4042768111017E | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 4042768111027G | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 4042761110044L | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 4042761110184X | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 4042761110274Y | IIa | N/A | HD 60151129 0001 #0197 |
| 4042761110304M | Ir | N/A | HD 60151129 0001 #0197 |
| 4042761110314P | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 4042761110334T | Ir | N/A | HD 60151129 0001 #0197 |
| 4042761110344V | Ir | N/A | HD 60151129 0001 #0197 |
| 40427611103855 | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 40427611103957 | Ir | N/A | HD 60151129 0001 #0197 |
| 4042761110404Q | IIa | N/A | HD 60151129 0001 #0197 |
| 4042761110414S | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 4042761110424U | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 4042761110434W | IIa | N/A | HD 60151129 0001 #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/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| 4042761110444Y | IIa | N/A | HD 60151129 0001 #0197 |
| 4042761111234V | IIa | N/A | HD 60151129 0001 #0197 |
| 40427611114353 | IIa | N/A | HD 60151129 0001 #0197 |
| 40427611104552 | IIa | N/A | HD 60151129 0001 #0197 |
| 4042761110495A | IIa | N/A | HD 60151129 0001 #0197 |
| 4042761110504T | IIa | N/A | HD 60151129 0001 #0197 |
| 4042761110514V | IIa | N/A | HD 60151129 0001 #0197 |
| 4042761110524X | IIa | N/A | HD 60151129 0001 #0197 |
| 4042761110534Z | IIa | N/A | HD 60151129 0001 #0197 |
| 40427611105453 | IIa | N/A | HD 60151129 0001 #0197 |
| 4042761110585B | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 4042761110595D | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 4042761110604W | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 4042761110614Y | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 4042761110675C | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 40427611107255 | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 40427611107357 | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 4042761110755B | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 4042761110845C | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 4042761110875J | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 4042761110925B | IIb non-implantable | N/A | HD 60151129 0001 #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/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| 4042761110935D | IIa | N/A | HD 60151129 0001 #0197 |
| 4042761110945F | IIa | N/A | HD 60151129 0001 #0197 |
| 4042761110965K | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 4042761110975M | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 4042761110985P | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 40427611111854 | IIa | N/A | HD 60151129 0001 #0197 |
| 4042761110995R | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 4042761111004H | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 4042761111034P | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 4042761111044R | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 4042761111054T | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 4042761111074X | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 4042761111084Z | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 40427611110953 | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 4042761111104L | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 4042761111114N | Ir | N/A | HD 60151129 0001 #0197 |
| 4042761111124Q | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 4042761111134S | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 4042761111144U | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 40427611111752 | IIb non-implantable | N/A | HD 60151129 0001 #0197 |
| 40427611111956 | IIa | N/A | HD 60151129 0001 #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/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| 4042761111204P | IIa | N/A | HD 60151129 0001 #0197 |
| 4042761111224T | IIa | WA22018A<br>WA22019A<br>A22021A<br>A22022A<br>A22023A<br>A22026A<br>A22027A<br>A42021A | HD 60151129 0001 #0197 |
| 40427611112653 | IIa | A22051A<br>A22053A<br>A22054A | HD 60151129 0001 #0197 |

**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 |
|---|---|---|---|
| 40427611114353 | IIa | WA33039A | Notified body involvement not required pursuant to MDD |
| 40427611114455 | IIa | N/A | Notified body involvement not required pursuant to MDD |
| 4042761111495F | IIa | N/A | Notified body involvement not required pursuant to MDD |
| 40427611115458 | IIa | N/A | Notified body involvement not required pursuant to MDD |
| 4042761111555A | IIa | N/A | Notified body involvement not required pursuant to MDD |
| 4042761111565C | IIa | N/A | Notified body involvement not required pursuant to MDD |
| 4042761111595J | IIa | N/A | Notified body involvement not required pursuant to MDD |
| 40427611116155 | IIa | N/A | Notified body involvement not |

| 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 |
|---|---|---|---|
| | | | required pursuant to MDD |
| 4042761111655D | Ir | N/A | Notified body involvement not required pursuant to MDD |
| 40427611117056 | Ir | N/A | Notified body involvement not required pursuant to MDD |
| 4042761111725A | Ir | N/A | Notified body involvement not required pursuant to MDD |
| 4042761111745E | IIa | N/A | Notified body involvement not required pursuant to MDD |
| 4042761111755G | Ir | N/A | Notified body involvement not required pursuant to MDD |
| 4042761111785N | IIa | A02908A | Notified body involvement not required pursuant to MDD |
| 4042761110354X | Ir | N/A | Notified body involvement not required pursuant to MDD |
| 4042761110364Z | Ir | N/A | Notified body involvement not required pursuant to MDD |
| 40427611103753 | Ir | N/A | Notified body involvement not required pursuant to MDD |
| 40427611111854 | IIa | N/A | Notified body involvement not required pursuant to MDD |
| 4042761111234V | IIa | N/A | Notified body involvement not required pursuant to MDD |
| 4042761111254Z | IIa | N/A | Notified body involvement not required pursuant to MDD |
| 4042761111244X | IIa | N/A | Notified body involvement not required pursuant to MDD |
| 4042761110324R | Ir | N/A | Notified body involvement not required pursuant to MDD |
| 4042761111214R | IIa | N/A | Notified body involvement not required pursuant to MDD |

| 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 |
|---|---|---|---|
| 4042761111665F | Ir | N/A | Notified body involvement not required pursuant to MDD |

## Confirmation Letter Revision History

| Date | NB internal reference traceable to each version of the letter | Action |
|---|---|---|
| 2024/04/18 | OSTE_CL607_2024-04-18.pdf | Initial issue |
| 2024/04/24 | OSTE_CL607_2024-04-24.pdf | Correction of MDR device classification of 40427611114659 to class IIb non-implantable<br><br>Correction of the substitute device of 4042761111485D (A37025A)<br><br>Adding of a MDR device class IIa to 4042761111775L<br><br>Adding the devices 40427611114353, 4042761111234V under a MDD Certificate<br><br>Change that the device 4042761111595J required not a Notified body<br><br>Change that the device 40427611111854 referred to a MDD certificate |
| YYYY/MM/DD | XXXXXXXXX | Removal of device XYZ to the list |

OLYMPUS

# EC – DECLARATION OF CONFORMITY
## EG - KONFORMITÄTSERKLÄRUNG

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| | |
|---|---|
| **Manufacturer:**<br>*Hersteller:* | **Olympus Winter & Ibe GmbH**<br>Kuehnstr. 61 / 22045 Hamburg / Germany<br>P.O. Box 70 17 09 / 22017 Hamburg / Germany<br>Phone: +49 (40) 6 69 66-0 / Fax: +49 (40) 6 69 66-2109 |
| **Single Registration Number from the Manufacture**<br>*Einmalige Registriernummer des Herstellers* | **DE-MF-000006729** |
| **Place of issue of the declaration**<br>*Ort der Ausstellung der Erklärung* | **Hamburg** |

**The manufacturer declares for the products described in Attachment 1 (List of related articles) the compliance with the requirements of following European Regulations and Directives:**

*Der Hersteller erklärt für die in Anhang 1 (Liste der zugehörigen Artikel) beschriebenen Produkte die Erfüllung der Anforderungen der folgenden Europäischen Richtlinien und Verordnungen:*

| | | |
|---|---|---|
| ☒ | REGULATION (EU) 2017/745 | **Medical Device Regulation**<br>*Medizinprodukte Verordnung* |
| ☒ | DIRECTIVE 2011/65/EU | **RoHS Directive**<br>*RoHS Richtlinie* |
| ☐ | DIRECTIVE 2014/53/EU | **Radio Equipment Directive**<br>*Funkanlagenrichtlinie* |
| ☐ | DIRECTIVE 2006/42/EC | **Machinery Directive**<br>*Maschinenrichtlinie* |