**Notified Body Confirmation Letter Reference: C605879**

To whom it may concern,

**Confirmation of receipt of a formal application and conclusion of written agreement in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices.**

This letter confirms that, DNV Product Assurance AS, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 2460 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:

BTL Industries Limited

161 Cleveland Way, Stevenage, Hertfordshire

SG1 6BU United Kingdom

The devices covered by the formal application and the written agreement mentioned above are listed in Table 1 below.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer submitted the MDR application and signed the written agreement by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation/exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR 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 120.3 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

Place and date:
**Høvik, 2023/04/25**

For the issuing office:
**DNV Product Assurance AS – Notified Body 2460**
**Veritasveien 1, 1363 Høvik, Norway**

C. Rajesh Kumar

**Rajesh Kumar Chellappan**
Management Representative

- 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)

**Table 1: Devices covered by this letter:**

| Device name / Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified at the quotation request review 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 |
|---|---|---|---|
| BTL-6000 Microwave/ ++B108018POEUXP | IIa | BTL-6000 Microwave | Certificate number: 10407-2017-CE-CZS-NA-PS Rev. 2.0<br>Expiry date: 27 May, 2024<br>NB number: 2460 |
| BTL-CPMotion ++B108093POEUZ8 | IIa | BTL-CPMotion | Certificate number: 10409-2017-CE-CZS-NA-PS Rev. 2.0<br>Expiry date: 27 May, 2024<br>NB number: 2460 |
| BTL-6000 TR-Therapy ++B108049POEUZ9 | IIa | BTL-6000 TR-Therapy | Certificate number: 10410-2017-CE-CZS-NA-PS Rev. 2.0<br>Expiry date: 27 May, 2024<br>NB number: 2460 |
| Exilis / Exilis Elite ++B108715POEEUYZ | IIb | Exilis - (Exilis/Exilis Elite) | Certificate number: 10412-2017-CE-CZS-NA-PS Rev. 4.0<br>Expiry date: 11 December, 2023<br>NB number: 2460 |
| Exilis Ultra 360/ ++B108715POUEU3L | IIb | Exilis - (Exilis Ultra 360) | Certificate number: 10412-2017-CE-CZS-NA-PS Rev. 4.0<br>Expiry date: 11 December, 2023<br>NB number: 2460 |
| BTL-Vac II/ ++B108042POEUWU | IIa | BTL-Vac II | Certificate number: 10414-2017-CE-CZS-NA-PS Rev. 2.0<br>Expiry date: 26 July, 2023<br>NB number: 2460 |
| BTL-4000 Smart/ Premium ++B108058POEUZB (Class IIa)<br>++B108058POBEUXQ (Class IIb) | IIb<br>IIa | BTL-4000 Smart/ Premium | Certificate number: 10414-2017-CE-CZS-NA-PS Rev. 2.0<br>Expiry date: 26 July, 2023<br>NB number: 2460 |
| BTL-5000 Series ++B108038POEUYH (Class IIa)<br>++B108038POBEUWN (Class IIb) | IIb<br>IIa | BTL-5000 Series | Certificate number: 10416-2017-CE-CZS-NA-PS Rev. 2.0<br>Expiry date: 14 April, 2023<br>NB number: 2460 |
| BTL-6000 Shortwave/ ++B108013POFD | IIb | BTL-6000 Shortwave | Certificate number: 10417-2017-CE-CZS-NA-PS Rev. 2.0<br>Expiry date: 14 April, 2023<br>NB number: 2460 |
| BTL-6000 Lymphastim/ ++B108011POEUVA | IIa | BTL-6000 Lymphastim | Certificate number: 10418-2017-CE-CZS-NA-PS Rev. 2.0;<br>Expiry date: 14 April, 2023<br>NB number: 2460 |
| BTL-6000 Super Inductive | IIa | BTL-6000 Super Inductive | Certificate number: 10406- |

| Device name / Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified at the quotation request review 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 |
|---|---|---|---|
| System<br>++B108099POELEU5Q | | System | 2017-CE-CZS-NA-PS rev. 2.0<br>Expiry date: 27 May, 2024<br>NB number: 2460; |
| BTL EMSELLA<br>++B108099POEMEU5V | IIa | BTL EMSELLA | Certificate number: 12056-2018-CE-CZS-NA-PS Rev. 2.0<br>Expiry date: 27 May, 2024<br>NB number: 2460 |
| BTL-6000 FSWT<br>++B108094POEUZK | IIb | BTL-6000 FSWT | Certificate number: 10000418361-PA-NA-CZE rev.0.0.<br>Expiry date: 27 May, 2024<br>NB number: 2460 |

**Confirmation Letter Revision History**

| Date | NB internal reference traceable to each version of the letter | Action |
|---|---|---|
| 2023/04/24 | C605879 | Initial issue |
| 2023/04/25 | C605879 | Deleted MDD Certificate numbers |

## Lack of fulfilment of conditions

The following may render this letter of confirmation invalid:

- Lack of compliance to the requirements of Regulation (EU) 2023/607
- Significant changes to design or intended purpose of the devices
- Changes in the quality system affecting production
- Periodical audits not held within the timeframe