



**Notified Body Confirmation Letter Reference: C615581**

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, 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:

**Angelus Industria de Produtos Odontológicos S/A**  
**Rua Waldir Landgraf, 101 – Londrina – PR Brazil - 86031-218**

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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a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

Place and date:  
Høvik, 2023/06/05

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



**Rajesh Kumar Chellappan**  
Management Representative

- 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)

**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 quotation request review 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 |
|---|--|--|--|
| NA  |  |  |  |

**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 device | MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|--|---|--|--|
| <b>GLASS FIBER POSTS AND KITS</b><br><br><b>BASIC UDI-DI:</b><br><b>807865POSTSMZ</b><br><br><b>EXACTO</b><br>915 - EXACTO Refill No 1<br>916 - EXACTO Refill No 2<br>917 - EXACTO Refill No 3<br>9097 - EXACTO Translucent Refill No 0.5<br>9157 - EXACTO Translucent Refill No 1<br>9167 - EXACTO Translucent Refill No 2<br>9177 - EXACTO Translucent Refill No 3<br>10216 - Surgi POST Multiconical 2 FV (private/commercial brand of EXACTO)<br>10217 - Surgi POST Multiconical 3 FV (private/commercial brand of EXACTO)<br>10218 - Surgi POST Multiconical 4 FV (private/commercial brand of EXACTO)<br>10219 - Surgi POST Multiconical 6 FV (private/commercial brand of EXACTO)<br>10220 - Surgi POST Multiconical 8 FV (private/commercial brand of EXACTO)<br>10221 - Surgi POST Multiconical 10 FV | IIa   | N/A  | <b>Certificate#1434-MDD-278/2021</b><br><b>NB# 1434</b><br><b>Expire Date: 15/06/2023</b>    |

|   |     |     |  |
|---|-----|-----|--|
| <p>(private/commercial brand of EXACTO)<br/>           911 - EXACTO Trial Kit No 1<br/>           912 - EXACTO Trial Kit No 2<br/>           913 - EXACTO Trial Kit No 3<br/>           914 - EXACTO Kit<br/>           9087 - EXACTO Translucent Trial Kit No 0.5<br/>           9117 - EXACTO Translucent Trial Kit No 1<br/>           9127 - EXACTO Translucent Trial Kit No 2<br/>           9137 - EXACTO Translucent Trial Kit No 3<br/>           9147 - EXACTO Translucent Kit</p> <p><b>REFORPIN</b><br/>           796 - REFORPIN 05 units<br/>           797 - REFORPIN 10 units</p> <p><b>REFORPOST GLASS FIBER</b><br/>           721 - REFORPOST GLASS FIBER Refill No 1:<br/>           05 units<br/>           722 - REFORPOST GLASS FIBER Refill No 2:<br/>           05 units<br/>           723 - REFORPOST GLASS FIBER Refill No 3:<br/>           05 units<br/>           724 - REFORPOST GLASS FIBER Mini Kit<br/>           726 - REFORPOST GLASS FIBER Refill No 1:<br/>           10 units<br/>           727 - REFORPOST GLASS FIBER Refill No 2:<br/>           10 units<br/>           728 - REFORPOST GLASS FIBER Refill No 3:<br/>           10 units<br/>           10211 - Surgi POST F6 0,8 (private/commercial<br/>           brand of REFORPOST GLASS FIBER)<br/>           10212 - Surgi POST F6 1,0 (private/commercial<br/>           brand of REFORPOST GLASS FIBER)<br/>           10213 - Surgi POST F6 1,2 (private/commercial<br/>           brand of REFORPOST GLASS FIBER)<br/>           10214 - Surgi POST F6 1,4 (private/commercial<br/>           brand of REFORPOST GLASS FIBER)<br/>           10215 - Surgi POST F6 1,6 (private/commercial<br/>           brand of REFORPOST GLASS FIBER)<br/>           720 - REFORPOST GLASS FIBER Total Kit</p> <p><b>SPLENDOR</b><br/>           6258 - SPLENDOR Post and Sleeve Refill<br/>           6253 - SPLENDOR Drill Refill<br/>           6254 - SPLENDOR Kit</p> |     |     |  |
| <p><b>REINFORCEMENT FIBER</b></p> <p><b>BASIC UDI-DI:<br/>           807865FIBERSAU</b></p> <p>483 INTERLIG - 3 sachets<br/>           48346 DEI experience Glass Fibre Splint - 6<br/>           fibers (private/commercial brand of 483<br/>           INTERLIG)<br/>           47246 DEI experience Multi Fibre Bridge - 2<br/>           fibers (private/commercial brand of 483<br/>           INTERLIG)</p>   | IIa | N/A | <p><b>Certificate#</b>1434-MDD-<br/>           278/2021<br/> <b>NB#</b> 1434<br/> <b>Expire Date:</b> 15/06/2023</p> |
| <p><b>STEEL DRILLS</b></p> <p><b>BASIC UDI-DI:<br/>           807865DRILLSF7</b></p>  | IIa | N/A | <p><b>Certificate#</b>1434-MDD-<br/>           278/2021<br/> <b>NB#</b> 1434<br/> <b>Expire Date:</b> 15/06/2023</p> |

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|--|--|--|--|
| <p><b>EXACTO DRILL</b><br/> 1908 EXACTO DRILL No 0.5 - 1 unit<br/> 1911 EXACTO DRILL No 1 - 1 unit<br/> 1912 EXACTO DRILL No 2 - 1 unit<br/> 1913 EXACTO DRILL No 3 - 1 unit</p> <p><b>PEESO DRILL</b><br/> 162 PEESO DRILL No 1 - 1 unit<br/> 164 PEESO DRILL No 2 - 1 unit<br/> 166 PEESO DRILL No 3 - 1 unit<br/> 168 PEESO DRILL No 4 - 1 unit<br/> 170 PEESO DRILL No 5 - 1 unit<br/> 172 PEESO DRILL No 6 - 1 unit</p> <p><b>GATES DRILL</b><br/> 1962 GATES DRILL No 1 - 1 unit<br/> 1964 GATES DRILL No 2 - 1 unit<br/> 1966 GATES DRILL No 3 - 1 unit<br/> 1968 GATES DRILL No 4 - 1 unit<br/> 1970 GATES DRILL No 5 - 1 unit<br/> 1972 GATES DRILL No 6 - 1 unit</p> |  |  |  |
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**Confirmation Letter Revision History**

| <b>Date</b> | <b>NB internal reference traceable to each version of the letter</b> | <b>Action</b> |
|-------------|--|---------------|
| 2023/06/05  | C615581  | Initial issue |

**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