Information on transitional period Regulation (EU) 2017/745

We like to inform you about the new Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 as regards to the transitional provisions for certain medical devices.

With this regulation the transitional period laid out in Article 120 of Regulation (EU) 2017/745 was extended as follows:

Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC ***from 25 May 2017 that were still valid on 26 May 2021 and that have not been withdrawn afterwards shall remain valid after the end of the period indicated on the certificate until the date set out in paragraph 3a*** *of this Article applicable for the relevant risk class of the devices.* ***Certificates issued*** *by notified bodies in accordance with those Directives* ***from 25 May 2017 that were still valid on 26 May 2021*** *and that* ***have expired before 20 March 2023*** *shall be considered to be valid […] if one of the following conditions is fulfilled:*

(a) ***before the date of expiry of the certificate, the manufacturer and a notified body have signed a written agreement*** *in accordance with Section 4.3, second subparagraph, of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device;*

(b) a competent authority of a Member State has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59 (1) of this Regulation or has required the manufacturer, in accordance with Article 97 (1) of this Regulation, to carry out the applicable conformity assessment procedure.'

Based on this condition the following validity dates apply for our products:

3a. Devices which have a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and that is valid by virtue of paragraph 2 of this Article may be placed on the market or put into service until the following dates:

(a) ***31 December 2027, for all class III devices, and for class IIb implantable devices*** *except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors;*

(b) ***31 December 2028, for class IIb devices*** *other than those covered by point (a) of this paragraph,* ***for class IIa devices, and for class I devices*** *placed on the market in sterile condition or having a measuring function*

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Extension Requirements

In order to fulfil the requirements, set out in Regulation (EU) 2023/607 the following conditions must be met by the manufacturer and the respective devices:

- The products must still **comply with the Directive 93/42/EEC** requirements (MDD).
- The devices are **not subject to significant changes** in design and intended use.
- There must be **no unacceptable risk to patient health and safety**.
- A **quality management system** in accordance with Article 10(9) of Regulation (EU) 2017/745 must be in place by 26.05.2024.
- The formal **applications for certification** of the "Legacy Devices" must be **submitted by 26 May 2024**.
- The **Notified Body** must **confirm the application** in writing by 26 September 2024.

Note:

(1) implantcast has a **quality management system** according to Regulation (EU) 2017/745 in place including the respective certification which is also available on the **implantcast cloud**:

Certificates > MDR (EU) 2017/745 > QMS

(2) **DNV MedCert** has issued and continue to issue **confirmation letters** for the products which have been submitted for certification which are also available on the **implantcast cloud**:

Certificates > MDR (EU) 2017/745 > Confirmation Letters > DNV MedCert

Information on transitional period Regulation (EU) 2017/745

Transitional periods

The following transitional periods apply to the so-called legacy devices:

- Class III and IIb implantable until **31. December 2027**
- Class IIa and I (I_R) until **31. December 2028**

The new transitional periods lead to the following new **validity dates of the certificates**:

EC Design Examination Certificate (93/42/EEC) (class III products)

Product	Validity Date old	Validity Date new
MUTARS® Prox. Femur	03.04.2022	31.12.2027
MUTARS® MK/ HD	03.04.2022	31.12.2027
MUTARS® LUMiC	03.04.2022	31.12.2027
MUTARS® RS System	03.04.2022	31.12.2027
MUTARS® M-O-M	03.04.2022	31.12.2027
MUTARS® PEEK	03.04.2022	31.12.2027
MUTARS® RS Cup	03.04.2022	31.12.2027
MUTARS® Silver	03.04.2022	31.12.2027
AGILON®	29.08.2022	31.12.2027
EcoFit® 2M	28.10.2022	31.12.2027
Bicana®	12.11.2022	31.12.2027
EcoFit® Hip Stem	04.02.2024	31.12.2027
BIOLOX® (Femoral Heads /Inserts)	26.05.2024	31.12.2027
ACS® Knee System	27.05.2024	31.12.2027
5C® Knee System	27.05.2024	31.12.2027
AIDA®	27.05.2024	31.12.2027
DiaLoc® Hip Stem	27.05.2024	31.12.2027
ic-Heads / ic-bipolar Heads	27.05.2024	31.12.2027
Hip Cups/Inlays	27.05.2024	31.12.2027
ic-Straight Stem	27.05.2024	31.12.2027

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EC Certificate of Conformity (93/42/EEC)

Product	Validity Date old	Validity Date new	Comment
AAA® Ankle Joint System	27.05.2024	31.12.2027	Up-classified to class III according to Regulation (EU) 2017/745
TARiC® Ankle Joint System			
Nes Elbow System			
CarpoFit®			
ICARA®			
HAPTiC®			
MUTARS® Attachment Tube			
MUTARS® Diaphyseal Implant / MUTARS® Humerus Diaphyseal Implant	27.05.2024	31.12.2027	Remain class IIb (implantable)
MUTARS® Arthrodesis / RS Arthrodesis			
Metal Augments Hip *(EPORE® Acetabular Spacer, MUTARS® PRS, Buttress, Shim, Restrictor)*	27.05.2024	31.12.2028	Remain class IIb (Exceptions of „Class IIb implantable“)
EPORE® Cones			
ic-Cerclage			
Cempadic			
Intramedullary Plug			
Bone Screws			
Subsider			

For all legacy instruments the transition period until 31.12.2028 applies.

Information on transitional period Regulation (EU) 2017/745

Discontinued products

For products which are discontinued, **no new transitional periods** apply, and they can therefore be sold until **max. 26.05.2024**. The respective certificate validity dates are the corresponding last days of sale.

Discontinued products

Product	Validity Date
CAPICA®	**15.09.2021**
EcoFit® CDH	**19.12.2021**
KAI	**03.04.2022**
MUTARS® Filia	**03.04.2022**
Actinia® Revision stem with collar cementless	**09.04.2022**
AJS®	**27.08.2022**
Bicana® hip stem cemented length 170 mm	**12.11.2022**
MUTARS® Humerus Filia	**12.11.2022**
EcoFit® hip stem Coxa Vara cementless standard T-HA	**04.02.2024**
BethaLoc® (only EU)	**06.02.2024**
ic-head BIOLOX® delta Ø44 mm	**27.05.2024**
ic-head BIOLOX® forte	**27.05.2024**
EcoFit® hip cup EPORE® / TCP NH	**27.05.2024**
Ceraco® hip cup ROM	**27.05.2024**
Ceraco® hip stem	**27.05.2024**
Cortina® hip stem	**27.05.2024**
ic-unipolar head	**27.05.2024**
Recartic® knee	**27.05.2024**
ic acetabular ring / ic reinforcement cage	**27.05.2024**
CCI® ankle joint	**27.05.2024**
Utility®	**27.05.2024**
Trochanter Plate	**27.05.2024**

Additional discontinued products:

Range of sizes within the following systems: ACS® / MUTARS® / AGILON® / EcoFit® 2M / ICARA®.

Information on transitional period Regulation (EU) 2017/745

Certificates / DoC

EC Design Examination Certificate (93/42/EEC) and the corresponding **Declarations of Conformity (DoC)** are **not issued** with a new issuance or validity date. The existing certificates and DoC only state the existing expiry date by the time of issuance.

DNV MedCert has issued and continue to issue **confirmation letters** for the products which have been submitted for certification which are also available on the **implantcast cloud**. An additional Manufacturer Declaration has been issued is also available on the **implantcast cloud**.

- **Certificates > MDR (EU) 2017/745 > Confirmation Letters > DNV MedCert**
- **Certificates > MDR (EU) 2017/745 > Confirmation Letters > Manufacturer Declaration**

DNV

To whom it may concern

DNV MEDCERT GmbH
Pilatuspool 2
20355 Hamburg
Germany

Tel: +49 40 2263325-0
E-mail: Medcert-Info@dnv.com

Date: 2023-08-07

Our reference: QS-7092, PP-13195, PP-13226, PP-13261, PP-13211, PP-13185

Notified Body Confirmation Letter
Certification No: 7092GB454230807

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

To whom it may concern,

This letter confirms that DNV Medcert GmbH, a Notified Body (NB), designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0482 on Nando[1], 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.

implantcast GmbH
Lüneburger Schanze 26
21614 Buxtehude
Germany
SRN[2]: DE-MF-000010002

The devices covered by the formal application and the written agreement mentioned above are identified in the tables (in the appendix of this letter). Table 1 identifies the devices for which an MDR application has been received, a 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.

Note: Please use these writings by DNV MedCert for official requests in combination with the existing certificates and DoC's once they have been issued to us.

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Derogations / Concession Letters

The existing derogations acc. to article 59 and the writings acc. to article 97 (1) by the State Trade Supervisory Authority Lüneburg will become obsolete. The CE mark acc. to MDD 93/42/EEC will become valid again and supersede the writings and notifications.

The corresponding confirmation letters by the State Trade Supervisory Authority Lüneburg certificate are available on the **implantcast cloud**:

- **Certificates > MDR (EU) 2017/745 > Confirmation Letters > State Trade Supervisory Authority Lüneburg**

Cancellation of sell-off period

Up to now, there has been a sell-off period laid out in Article 120 (4) of Regulation (EU) 2017/745 for the European distributors for products that **have been discontinued** until 26.05.2025. This sell-off period will now be cancelled without replacement in Regulation (EU) 2023/607:

Devices lawfully placed on the market pursuant to Directives 90/385/EEC and 93/42/EEC prior to 26 May 2021, and devices lawfully placed on the market from 26 May 2021 pursuant to paragraphs 3, 3a, 3b and 3f of this Article, may continue to be made available on the market or put into service.';

This means that our European customers can continue to market the discontinued products after 2025 until the sterilization date has expired. **A re-sterilization of these products is not possible.**