SZUTEST
Konformitätsbewertungsstelle GmbH

NOTIFIED BODY CONFIRMATION LETTER
No: MD0071-CL-01

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 Regulation (EU) 2017/745 and implementing Regulation (EU) 2023/1194 amending implementing Regulation (EU) 2022/2346 as regards the transitional provisions for certain medical devices.

This letter confirms that **SZUTEST Konformitätsbewertungsstelle GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2975** 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:

Company Name	OSİMPLANT TIBBİ MALZEMELER MEDİKAL TİC. LTD. ŞTİ.
Address	Mustafa Kemal Mah. 2133. Sk. No:4/2 ÇANKAYA ANKARA/TÜRKİYE
SRN Number (if available)	TR-MF-000014782

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 SZUTEST Konformitätsbewertungsstelle GmbH 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 SZUTEST Konformitätsbewertungsstelle GmbH has not yet taken 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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a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 with the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 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
- 31 December 2028 for Annex XVI products which do not require a clinical investigation.
- 31 December 2029 for Annex XVI products which require a clinical investigation.

On behalf of SZUTEST Konformitätsbewertungsstelle GmbH,

MEHMET IŞIKLAR
General Manager

SZUTEST Konformitätsbewertungsstelle GmbH-NB 2975
Friedrich-Ebert-Anlage 36 D-60325 Frankfurt am Main /GERMANY

To check the validity of this confirmation letter please scan the barcode. To manually check, go to https://public.szutest-germany.de/ use the first 3 digits of the manufacturer name and confirmation letter No. For further information please contact md_confirmation@szutest-germany.de

Table 1: Devices covered by this letter and for which SZUTEST Konformitätsbewertungsstelle GmbH 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
Sterile & Non-Sterile Spinal Fixation Systems -AURA Anterior Cervical Plate System -STRATOS Interspinous Fixator Spinal Fixation System -CERES Minimally Invasive, Percutaneous Screw Spinal Fixation System -ATHENA MIS and Open Modular Pedicle Screw System	Class IIb	Same	Certificate #1; 1984-MDD-15-320 Issue Date: 02.01.2015 Expiry Date: 27.05.2024 NB1984: Kiwa Belgelendirme Hizmetleri A.Ş.
Sterile & Non-Sterile Spinal Fixation Systems -PORTHOS Posterior Cervical Spinal Fixation System -JUVE Pediatric Spinal Fixation System -OSI Spinal Fixation System -ON PLUS Spinal Fixation System -VESTA Cement Injectable Screw Spinal Fixation System	Class III	Same	Certificate #1; 1984-MDD-15-320 Issue Date: 02.01.2015 Expiry Date: 27.05.2024 NB1984: Kiwa Belgelendirme Hizmetleri A.Ş.
Sterile & Non-Sterile Spinal Cages -TERRACOTTA-C Trabecular Titanium Cervical Cage -ANTENOR Stand Alone ALIF Cage -ZELOS PEEK-TITANIUM PLIF Cage -ARIA Expandable PEEK PLIF Cage -FIDES Angular PEEK TLIF Cage -TALOS PEEK TLIF Cage -TERRACOTTA Trabecular Titanium Lumbar Interbody PLIF Cage -TERRACOTTA Trabecular Titanium Lumbar Interbody TLIF Cage -ARION Expandable Bladed Cervical PEEK Cage -BIA Cervical PEEK Cage -EOS Bladed Cervical PEEK Cage -TITANOPEEK ACF Stand Alone Cervical Cage System -X-XP Corpectomy Cage	Class III	Same	Certificate #1; 1984-MDD-15-320 Issue Date: 02.01.2015 Expiry Date: 27.05.2024 NB1984: Kiwa Belgelendirme Hizmetleri A.Ş.

Sterile Vertebroplasty and Kyphoplasty Kits -ON PLUS Gauge -ON PLUS Needle Beveled Type -ON PLUS Bone Filler -ON PLUS Osteo Introducer -ON PLUS Spacer (Drill) -Kirschner Wire -ILOS Spine Kit	Class IIa	Same	Certificate #1; 1984-MDD-15-320 Issue Date: 02.01.2015 Expiry Date: 27.05.2024 NB1984: Kiwa Belgelendirme Hizmetleri A.Ş.

Table 2: Devices covered by this letter and for which SZUTEST Konformitätsbewertungsstelle GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

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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
PAN Anterior Cervical Disc Prosthesis	Class III	Same	Certificate #1; 2195-MED-2114403 Issue Date: 24.05.2021 Expiry Date: 26.05.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş
ELYON Expandable Titanium Lumbar Interbody Cage	Class III	Same	Certificate #1; 2195-MED-2114403 Issue Date: 24.05.2021 Expiry Date: 26.05.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş
Surgical Instruments	Class Ir	Same	N/A

Confirmation Letter Revision History

Date	Version of the letter	Action
2024/05/21	MD0071-CL-01	Initial issue

Digitally signed by Buciaţchii Constantin
Date: 2025.09.05 11:42:01 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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