SZUTEST Konformitätsbewertungsstelle GmbH	NOTIFIED BODY CONFIRMATION LETTER

Company Name	SAYAN TIBBİ ALETLER PAZ. SAN. VE TİC. LTD. ŞTİ.
Address	Kemalpaşa Mah. 7110/2 Sokak No:4 35060 Bornova, İzmir, TÜRKİYE
Date	18.10.2023

NOTIFIED BODY CONFIRMATION LETTER
Reference: MD0009-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 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	SAYAN TIBBİ ALETLER PAZ. SAN. VE TİC. LTD. ŞTİ.
Address	Kemalpaşa Mah. 7110/2 Sokak No:4 35060 Bornova, İzmir, TÜRKİYE
SRN Number (if available)	TR-MF-000015714

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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a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 (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of SZUTEST Konformitätsbewertungsstelle GmbH,

SZUTEST
Konformitätsbewertungsstelle GmbH
Friedrich-Ebert-Anlage 36
60325 Frankfurt am Main

Signature
MEHMET IŞIKLAR
General Manager

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

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
N/A	N/A	N/A	N/A

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:

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
Plate & Screw System *Device 1*	Class IIb excluding Class IIb implantable non-WET	Same	Certificate #1: 2195-MED-1326001 Rev No: 04 Revision Date:13.11.2019 Expiry Date:26.05.2024 NB 2195 : Szutest Uygunluk Değerlendirme A.Ş.
Cable & Plate System *Device 2*	Class IIb excluding Class IIb implantable non-WET	Same	Certificate #1: 2195-MED-1326001 Rev No: 04 Revision Date:13.11.2019 Expiry Date:26.05.2024 NB 2195 : Szutest Uygunluk Değerlendirme A.Ş.
Surgical Instrument Bone Cutting System *Device 3*	Class IIa	Same	Certificate #1: 2195-MED-1315901 Rev No: 04 Revision Date:13.11.2019 Expiry Date:26.05.2024 NB 2195 : Szutest Uygunluk Değerlendirme A.Ş.
Surgical Instruments *Device 4*	Class I devices that qualify as re-usable surgical instruments	Same	N/A

Confirmation Letter Revision History

Date	Version of the letter	Action
2023/10/18	MD0009-CL-01	Initial Issue

For further information on the content of the letter or confirmation of the validity of the letter please contact md_confirmation@szutest-germany.de