

NOTIFIED BODY CONFIRMATION LETTER
No: MD0069-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	Acto GmbH
Address	Büchnerstrasse 11, 38118, Braunschweig, Germany
SRN Number (if available)	DE-MF-000019128

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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a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

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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
Wound Care Solution - Actolind® w Solution - Sutrissept® w Solution - Aclind® w Solution - Hydroclean® Solution - PREVENTIA® Surgical Irrigation - Tiritas® Wound Spray, - Cosmos® Wound Spray - DermaPlast® Wound Spray	Class III	Same	Certificate #1; M.2020.106.13506 Issue Date:13.04.2020 Expiry Date: 27.05.2024 NB2292: UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. Certificate #2; M.2020.106.13506-1 Issue Date:13.04.2020 Expiry Date: 27.05.2024 NB2292: UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş.
Invasive Medical Device Disinfectant - Actosed® Forte Ready - Actosed® OPA - Actosed® PA - Actosed® PA Powder - Actosed® Endo - Actosed® Endo Ready - Actosed® Endo Terra - Actosed® Enzym - Actosed® Plus - Actoclean® Flüssig - Actoclean® Perfect - Actodent® Bohrerbad	Class IIb	Same	Certificate #1; 1984-MDD-20-690 Issue Date:13.08.2020 Expiry Date: 27.05.2024 NB1984: Kiwa Belgelendirme Hizmetleri A.Ş.
Medical Device Surface Disinfectant - Actoanid® Foam - Actoanid® Spray - ActoFlyn® - Actosept® AF - Actosept® AF Citrus - Actodiacit® - Actodiacit® PA - Actosal Fläche AF New - Actoanid® Fläche New	Class IIa	Same	Certificate #1; 1984-MDD-20-690 Issue Date:13.08.2020 Expiry Date: 27.05.2024 NB1984: Kiwa Belgelendirme Hizmetleri A.Ş.



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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
Wound Care Solution Plus -Actolind Solution Plus -Sutrisept Solution Plus -Aclind Solution Plus -Hydroclean Solution Plus	Class III	Same	Certificate #1; 2195-MED-2010002 Issue Date:09.04.2020 Expiry Date: 26.05.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş. Certificate #2; 2195-MED-2010002-D03 Issue Date:13.04.2021 Expiry Date: 26.05.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Wound Care Gel - Actolind w Gel - Sutrisept w Gel - Aclind w Gel - Hydroclean Gel	Class III	Same	Certificate #1; 2195-MED-2010002 Issue Date:09.04.2020 Expiry Date: 26.05.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş. Certificate #2; 2195-MED-2010002-D01 Issue Date:13.04.2021 Expiry Date: 26.05.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Wound Care Gel Plus - Actolind Gel Plus - Sutrisept Gel Plus - Aclind Gel Plus - Hydroclean Gel Plus	Class III	Same	Certificate #1; 2195-MED-2010002 Issue Date:09.04.2020 Expiry Date: 26.05.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş. Certificate #2; 2195-MED-2010002-D02 Issue Date:13.04.2021 Expiry Date: 26.05.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Disinfectant Wipe - Actoanid® Wipes - Acto® Oxy Wipes - Actosept® AF Tücher	Class IIa	Same	Certificate #1; 2195-MED-2010002 Issue Date:09.04.2020 Expiry Date: 26.05.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.



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Medical Device Surface Disinfectant - Acto® Oxy Foam - Actosept® AF Plus	Class IIa	Same	Certificate #1; 2195-MED-2010002 Issue Date:09.04.2020 Expiry Date: 26.05.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Genital Care Lubricant Gel - Acto® Lubricant Gel - Acto® Sterile Lubricant Gel	Class IIb	Same	Certificate #1; 2195-MED-2010002 Issue Date:09.04.2020 Expiry Date: 26.05.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Invasive Medical Device Disinfectant - Actosed HP Ready	Class IIb	Same	Certificate #1; 2195-MED-2010002 Issue Date:09.04.2020 Expiry Date: 26.05.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.

Confirmation Letter Revision History

Date	Version of the letter	Action
2024/05/17	MD0069-CL-01	Initial Issue



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