NOTIFIED BODY CONFIRMATION LETTER
No: MD0039-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	DETRO HEALTHCARE KİMYA SANAYİ A.Ş.
Address	Atatürk Mah. Cemal Gürsel Cad. No:8 Esenyurt, İstanbul, TÜRKİYE
SRN Number (if available)	TR-MF-000022410

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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a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
Friedrich-Ebert-Anlage 36
60325 Frankfurt am Main
USt-IdNr. DE815819575
info@szutest-germany.de

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

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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
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
Endoscope Washer and Disinfector Device DW-5001 STR-5001 DW-6001 DW-6002 DW-6003 DW-6004 DW-8001 DW-8002 DW-8003 DW-8004 DW-5002 DW-5003 STR-5003 DW-5004 DW-5005 DW-6005 DW-7001 STR-7001 DW-7002 DW-7003 STR-7003 DW-7004 DW-7005 DW-8005	Class IIb	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expriy Date:28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Detro OPA (Orthophthalaldehyde)	Class IIb	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expriy Date:28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Detro Plus OPA (Orthophthalaldehyde)	Class IIb	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expriy Date:28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.

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Detro Plus (Glutaraldehyde)	Class IIb	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expriy Date:28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Detro Forte (Gluteraldehyde)	Class IIb	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expriy Date:28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Detrocid Endo (Alkyl Amine + QAC)	Class IIb	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expriy Date:28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Akadent (Alkyl Amine + QAC)	Class IIb	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expriy Date:28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Detrocid Endo Ready (Alkyl Amine + QAC)	Class IIb	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expriy Date:28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Akadent Ready (Alkyl Amine + QAC)	Class IIb	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expriy Date:28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Akadent Extra (Alkyl Amine + QAC)	Class IIb	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expriy Date:28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.

Detrocid Enzyme (Alkyl Amine + QAC)	Class IIb	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expriy Date:28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Detro PAA 1500 (1500 ppm peracetic acid)	Class IIb	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expriy Date:28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Detro PAA 2200 (2200 ppm peracetic acid)	Class IIb	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expriy Date:28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Detro Plus PAA (15% Peractic Acid)	Class IIb	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expriy Date:28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Detro Plus PAA DW (15% Peractic Acid)	Class IIb	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expriy Date:28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Detro Hemoplus (Citric Acid, Malic Acid, Lactic Acid)	Class IIb	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expriy Date:28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Detro Hemoplus PAA (Peractic Acid)	Class IIb	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expriy Date:28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.

Detrosept AF (Alcohol (30%) + QAC)	Class IIa	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expriy Date:28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Detro San AF (Alkyl Amine + QAC)	Class IIa	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expriy Date:28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Akaspray (Alcohol (60%) + QAC)	Class IIa	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expriy Date:28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Detrosan SFC (Alkyl Amine + QAC)	Class IIa	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expriy Date:28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Detro Spray (Alcohol (50%) + QAC)	Class IIa	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expriy Date:28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Detrosan HP Spray (Hydrogen Peroxide + Salicylic Acid)	Class IIa	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expriy Date:28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Detrosan SFC (Alkyl Amine + QAC)	Class IIa	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expriy Date:28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.

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Akaspray Tücher (Alcohol (60%) + QAC +Handkerchief Product Solutionimpregnated wipes)	Class IIa	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expriy Date:28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Detro San AF Wipes (Alkyl Amine + QAC+ Wipes Product: Solution Impregnated Wipes)	Class IIa	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expriy Date:28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.
Detro San HP Wipes (Hydrogen Peroxide + Salicylic Acid + Wipes Product: Solution Impregnated Wipes)	Class IIa	Same	Certificate #1; 2195-MED-1118102 Revision No: 13 Revision Date: 20.05.2021 Issue Date: 30.06.2011 Expriy Date:28.04.2024 NB2195: Szutest Uygunluk Değerlendirme A.Ş.

Confirmation Letter Revision History

Date	Version of the letter	Action
2024/03/08	MD0039-CL-01	Initial issue

Digitally signed by Lungu Ion
Date: 2025.06.27 17:01:44 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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