CE
0425

ICIM

Approvazione del Sistema Completo di Garanzia di Qualità
Full quality assurance system approval

Certificato N.
Certificate No. **0425-MED-004475-00**

Secondo l'allegato II, escluso (4) della Direttiva Europea 93/42/CEE (recepita con il Dlg n. 46 del 24.02.97)
According to Annex II, excluding (4) of EC Directive 93/42/CEE (as transposed into Dlg n. 46 issued on 24.02.97)

ORGANISMO NOTIFICATO / *NOTIFIED BODY*

ICIM S.p.A. - Identification number: 0425
Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI) - ITALY

VISTO L'ESITO DELLE VERIFICHE CONDOTTE IN CONFORMITÀ ALL'ALLEGATO II ESCLUSO (4) DELLA DIRETTIVA EUROPEA 93/42/CEE DICHIARA CHE IL SISTEMA COMPLETO DI GARANZIA DELLA QUALITÀ ATTUATO DA:
ON THE BASIS OF THE ASSESSMENT PERFORMED ACCORDING TO ANNEX II EXCLUDING (4) OF EC DIRECTIVE 93/42/CEE DECLARES THAT THE FULL QUALITY ASSURANCE SYSTEM ENFORCED BY:

TURKUAZ SAĞLIK HİZMETLERİ MEDİKAL TEMİZLİK KİMYASAL ÜRÜNLER SAN. VE TİC. A.Ş.

Registered Headoffice and Operatinve Unit
Akçaburgaz Mah. Muhsin Yazıcıoğlu Cad. No:45/5 34522 Esenyurt / İstanbul
Türkiye

PER I SEGUENTI TIPI DI PRODOTTI, PROCESSI, SERVIZI
FOR THE FOLLOWING KINDS OF PRODUCTS, PROCESSES, SERVICES

Sterile nasal solution e Sterile nasal solution mint
First Aid Burn Gel and Burn Dressing

È CONFORME AI REQUISITI / *IS IN COMPLIANCE WITH REQUIREMENTS*

Allegato II ESCLUSO (4) della Direttiva Europea 93/42/CEE
Annex II EXCLUDING (4) of EC Directive 93/42/EEC

Per l'identificazione dei modelli di prodotto vedere l'Allegato / *For identification of the model type see Annex*

Il presente Certificato è da ritenersi valido solo se accompagnato dal relativo Allegato / *This Certificate is valid only with the relative Annex*

Gaetano Trizio
Rappresentante Direzione / Management Representative

ICIM S.p.A.

PRIMA EMISSIONE *FIRST ISSUE*	EMISSIONE CORRENTE *CURRENT ISSUE*	DATA DI SCADENZA *EXPIRING DATE*
25/05/2021	**25/05/2021**	**26/05/2024**

0601CM_01_IT

CE
0425

ICIM

Approvazione del Sistema Completo di Garanzia di Qualità
Full quality assurance system approval

ALLEGATO AL / *ANNEX TO*

Certificato N.
Certificate No. **0425-MED-004475-00**

Secondo l'allegato II, escluso (4) della Direttiva Europea 93/42/CEE (recepita con il Dlg n. 46 del 24.02.97)
According to Annex II, excluding (4) of EC Directive 93/42/CEE (as transposed into Dlg n. 46 issued on 24.02.97)

IDENTIFICAZIONE TIPOLOGIE E MODELLI
IDENTIFICATION OF THE MODEL/TYPE

Tipologia / Type: Soluzioni spray nasali sterili / *Sterile nasal solution e Sterile nasal solution mint*

Classe / *Class:* Is

PRODOTTO / PRODUCT	*GMDN CODICE / GMDN CODE*
Sterile nasal solution	*44844*
Sterile nasal solution mint	*44844*

Tipologia / Type: Gel Sterile per medicazioni / *Sterile First Aid Burn Gel and Burn Dressing*

Classe / *Class:* IIb

PRODOTTO / PRODUCT	*GMDN CODICE / GMDN CODE*
Sterile First Aid Burn Gel Bottle	*47693*
Sterile First Aid Burn Gel Sachet	*47693*
Sterile First Aid Burn Dressing	*47693*

Gaetano Trizio
Rappresentante Direzione / Management Representative

ICIM S.p.A.

PRIMA EMISSIONE *FIRST ISSUE*	EMISSIONE CORRENTE *CURRENT ISSUE*	DATA DI SCADENZA *EXPIRING DATE*
25/05/2021	**25/05/2021**	**26/05/2024**

0601CM_01_IT

NOTIFIED BODY CONFIRMATION LETTER
No: MD0064-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	Turkuaz Sağlık Hizmetleri Medikal Temizlik Kimyasal Ürünler San. ve Tic. A.Ş
Address	Akçaburgaz Mah. Muhsin Yazıcıoğlu Cad. No:45/5 Esenyurt, İstanbul, TÜRKİYE
SRN Number (if available)	TR-MF-000016026

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

YEMİNLİ TERCÜME NOTARY SWORN TRANSLATION

expert TERCÜME
DANIŞMANLIK LİMİTED ŞİRKE
Turgut Ozal Mah. 33. Sk. No:8
Atoport AVM Kat:5 Esenyurt İSTAN

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
Anti-Lice and Nits Spray -Topical Anti-Lice and Nits Spray 50 mL (STOPLICE) -Anti-Lice and Nits Spray 100 mL (KONİX) -Anti-Lice and Nits Spray 100 mL (BİTER) -Anti-Lice Spray 100 mL (BİONYT)	Class III	Same	Certificate #1; 301001343 Issue Date: 10.05.2021 Expiry Date: 24.05.2024 NB0653: NATIONAL EVALUATION CENTER OF QUALITY AND TECHNOLOGY IN HEALTH S.A.- EKAPTY
Sterile First Aid Burn Gel -Sterile First Aid Burn Gel Bottle (50 mL, 59 mL, 100 mL, 118 mL, 125 mL) -Sterile First Aid Burn Gel Sachet (3.5 gr, 5 gr, 10 gr, 20 gr)	Class III	Same	Certificate #1; 0425-MED-004475-00 Isssue Date: 25.05.2021 Expiry Date: 26.05.2024 NB0425: ICIM S.P.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
N/A	*N/A*	*N/A*	N/A

Confirmation Letter Revision History

Date	Version of the letter	Action
2024/05/23	MD0064-CL-01	Initial issue

YEMİNLİ TERCÜME NOTERİ SWORN TRANSLATION

Expert TERCÜME İŞ DANIŞMANLIK LİMİTED ŞİRKETİ Turgut Özal Mah. 33. Sk. No:8 Esenyurt AVM Kat:5 İSTANBUL

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