Le Verdier	FICHE TECHNIQUE	03/06/2026 DCE.FT.V826

Référence :	Nom du produit :
V826	**SACHET DE 5 SUTURES ADHESIVES STERILES 75 X 3 MM**

Conditionnement : Paquet de 5

Conditionné et distribué par : Le Verdier – Entreprise adaptée
540 Avenue Georges Pompidou – BP 2
18200 SAINT-AMAND-MONTROND CEDEX
Tél. + 33 (0)2 48 61 50 90 - Fax + 33 (0)2 48 61 50 99

Fournisseur : FARMOR

Référence : Boîte de 50 sachets de 5 sutures adhésives stériles - SUT 6033 AD

Version	Date	Historique des modifications	Rédaction	Approbation
1	26/11/2020	Création	Dossier Central	Responsable QHSE
2	03/06/2026	Mise à jour	Dossier Central	Responsable QHSE

FARMOR
CRÉATEUR DE PREMIERS SECOURS

FICHE TECHNIQUE

Boite de 50 sachets de 5 sutures adhésives stériles

Gamme **Urgence & Accessoires**

RÉFÉRENCE : **SUT 6033 AD**

Gencod :

Dimensions :
75 mm x 3 mm

DESCRIPTIF & PROPRIETES DU PRODUIT ACTIF

Sachet de 5 bandelettes adhésives blanches.

Referme de façon rapide et efficace les petites plaies superficielles.

EMBALLAGE

Boite de 50 sachets de 5 sutures

UTILISATION ET MODE D'EMPLOI

Vérifier l'intégrité du protecteur individuel de stérilité avant usage.
Usage unique.

Dispositif Médical de classe IIa, conforme au règlement européen 2017/745 soumis à obligation de traçabilité.

⇨ FRANCE

ATTESTATION

16 Avril 2024

Je soussigné, Aldric SCHELFHOUT, Pharmacien Affaires Réglementaires au nom des Laboratoires URGO, 42 rue de Longvic, 21300 Chenôve, France, agissant en tant que distributeur du dispositif médical suivant :

URGOSTRIPS, sutures chirurgicales adhésives stériles

Déclare que la déclaration du fabricant légal[1] de ce dispositif médical, Laboratoires URGO Healthcare, 42 rue de Longvic, 21300 Chenôve, France, indique une fin de validité prolongée du certificat 33524[2], délivré en vertu de la directive 93/42/CEE, au **31 Décembre 2028**.

LABORATOIRES URGO
42 rue de Longvic
21300 CHENOVE - FRANCE

Aldric SCHELFHOUT
Pharmacien Affaires Réglementaires
Laboratoires URGO

[1] *Manufacturer's self-declaration – Laboratoires URGO Healthcare*. Document annexé à la présente attestation.
[2] Certificat CE MDD. Document annexé à la présente attestation.

Manufacturer's Self-Declaration

in relation to Regulation 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	**Laboratoires URGO Healthcare (and SDPDM)**
Manufacturer address and contact details	**42 rue de Longvic 21300 Chenôve** **Email: c.soupe@fr.urgo.com**
Single Registration Number (SRN) (if available)	**FR-MF-000001538**

Authorised Representative name (if applicable)	**NA**
Authorised Representative address and contact details	**NA**
Single Registration Number (SRN) (if available)	**NA**

Notified body name (if applicable)	☒ **See attached schedule**
Notified body number (if applicable)	☒ **See attached schedule**
Directive Certificate number(s) to which this confirmation is made (if applicable)	☒ **See attached schedule**
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	☒ **See attached schedule**
End date of extended validity/transition period	☒ **See attached schedule**

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021, was/were not withdrawn by 20 March 2023
- *Choose applicable statements:*

☐ Expired *before* 20 March 2023:

☐ Before the original date of expiry as indicated on the Directive Certificate, we and the notified body have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device

☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request)

☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

☒Expired/expires *after* 20 March 2023:

☒A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

LABORATOIRES URGO HEALTHCARE I SAS au capital de 56 280 458 € I RCS DIJON 798 251 559 I TVA : FR 65 798 251 559 I SIRET 798 251 559 00026
Siège social : 42 rue de Longvic 21300 CHENÔVE I Tel : +33 (0)3 80 44 74 00

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☒A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

- *Choose one applicable statement:*

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☐ A QMS in accordance with Article 10(9) MDR is in place.

☒ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- The device(s) has/have not been significantly changed in its/their design and intended purpose since 26 May 2021.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name

Laboratoires URGO Healthcare (and SDPDM)

Location & Date

Chenôve, November 27, 2023

Signature, Print Name, Title

Caroline SOUPE, Person Responsible for Regulatory Compliance

Identification of the device Device name / Basic UDI-DI (under MDR application)	**MDR Device classification**	**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 (Name and number)**	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**End date of extended validity/transition period**
URGO Pansement spray, filmogel *URGO Dressing spray, filmogel* 3664492LUHUS0036PN	IIa	URGO "BLESSURES SUPERFICIELLES" PANSEMENT SPRAY, pansement filmogène *URGO " SUPERFICIAL WOUNDS" DRESSING SPRAY, liquid bandage* LUHUS0036	33524 GMED - 0459	May 26th, 2024	31/12/2028
Urgo Brûlures waterproof *URGO Burns waterproof* 3664492LUHUS0139PZ	IIa	URGO BRULURES WATERPROOF *URGO BURNS WATERPROOF* LUHUS0139	33524 GMED - 0459	May 26th, 2024	31/12/2028
URGOSTRIPS, sutures chirurgicales adhésives stériles *URGOSTRIPS, sterile adhesive surgical suture* 3664492LUHUS0007PF	IIa	URGOSTRIPS, sutures chirurgicales adhésives stériles *URGOSTRIPS, sterile adhesive surgical suture* LUHUS0007	33524 GMED - 0459	May 26th, 2024	31/12/2028
Mercurochrome Suture adhesives *Mercurochrome adhesives strips* 3664492LUHUS0007PF	IIa	MERCUROCHROME sutures adhésives *MERCUROCHROME adhesives strips* LUHUS0007	35323 GMED - 0459	May 26th, 2024	31/12/2028
URGO Stop Aphtes, filmogel®/ *URGO Stop Mouth ulcers, filmogel®* *CALADERM filmogel® Aftas* 3664492LUHUS0170PT	IIa	URGO Stop Aphtes, filmogel® *URGO Stop Mouth Ulcers, filmogel®* LUHUS0170	33524 GMED - 0459	May 26th, 2024	31/12/2028

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