Bureau Veritas Certification

Extract N°1 of EU quality assurance certificate N° IT340024-1

Issued to

TIASET DI CARRESI LORENZO

Via delle Cantine, 30 - 52022 Cavriglia (AR) – Italy

Single Registration number: **IT-MF-000027518**

Certified site(s)

Via delle Cantine, 30 - 52022 Cavriglia (AR) – Italy

Bureau Veritas Italia S.p.A. certifies that the production quality assurance system of the above mentioned manufacturer has been audited and it complies with the requirements of

Regulation (EU) 2017/745

(in accordance with annex XI part A)

In relation to the following Medical Device:

Model name (s):	DERMADRAPE
Generic group	Incision drapes, without antibacterial agent
Category	MDN 1204 - Non-active non-implantable devices for wound and skin care
Risk class	Is
Basic UDI-DI	805053472DERMADRAPETA
Specific conditions or limitations of validity of the certificate	The audit by Bureau Veritas Italia of the quality management system was limited to the aspects relating to establishing, securing and maintaining sterile conditions.

Certificate issue date: **19 Feb. 2025**
Subject to the continued satisfactory operation of the production quality assurance system, this certificate expires on: **18 Feb. 2030**

Certificate N°: IT340024 Version: **1** Issue date: **19 Feb. 2025**
Extract N°: 1 Version: **1** Issue date: **03 Mar. 2025**

Revision History	
Revision	Description
Revision n. IT340024-1 Revision date: 19 Feb. 2025	CER-F-093 20274884 1-20084899094 del 19 Feb. 2025: First issue approval

Gloria Focetola

GLORIA FOCETOLA - Local Technical Manager

This certificate is issued by Bureau Veritas Italia S.p.A. Viale Monza 375- 20126 Milano ITALY, notified body according to the Regulation (EU) 2017/745 with identification number 1370.

Information on examinations and tests performed regarding relevant CS and harmonized standards, relevant test reports and audit report(s) are in the dossier (FLEX n. 20274884) available on request from medical.device@bureauveritas.com