Unit 1b, Lynx Business Park, Fordham Road,
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E mail@tristel.com
@TristelGlobal
www.tristel.com
Tristel Solutions Ltd Company No. 03518312 **Tristel plc** Company No. 04728199 **Registered office** As above

In accordance with:

Article 22 of the Medical Device Regulations (EU) 2017/745 (as amended by Regulation (EU) 2023/607) EU MDR
and
UK Medical Devices Regulations 2002 (as amended)- Regulation 7 (Systems and Procedure Packs) UK MDR

Legal Manufacturer:

Tristel Solutions Limited, Unit 1b Lynx Business Park, Fordham Road, Snailwell, Newmarket, Cambridgeshire, CB8 7NY

Procedure Packs:

Procedure Packs Name	Product code	UDI-DI
Tristel Trio Wipes System (50)	TSL030601	05060171911180
Tristel Trio Wipes System (50)	TSL030609	05060171919681
Tristel Trio Wipes System (50)	TSL030610	05060171911821
Tristel Trio Wipes System (5)	TSL030801	05060171919308

Containing the following products:

Product name	Rule No.	Class
Tristel Pre-Clean Wipe	1 (EU MDR & UK MDR)	I
Tristel Sporicidal Wipe	16 (EU MDR) & 15 (UK MDR)	IIb
Tristel Rinse Wipe	1 (EU MDR & UK MDR)	Is

Above mentioned Procedure packs are assembled in accordance with:

- Article 22 of the Medical Device Regulations (EU) 2017/745 (as amended by Regulation (EU) 2023/607)
- UK Medical Devices Regulations 2002 (as amended)- Regulation 7 (Systems and Procedure Packs)

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Declaration
Tristel Solution Limited declares that:

- All medical devices included in this pack bear a valid **CE marking** (for EU market) and/or **UKCA marking** (for Great Britain), as applicable.
- Tristel Trio Wipes System is classified as a procedure pack as per Article 22 of the Medical Device Regulations (EU) 2017/745 (as amended by Regulation (EU) 2023/607) and UK Medical Devices Regulations 2002 (as amended)- Regulation 7 (Systems and Procedure Packs) and is intended for the high-level disinfection of non-lumened invasive, and non-invasive medical devices.
- Mutual compatibility of the medical devices mentioned above has been verified. The procedure packs are packaged, and relevant information are supplied to users. The combination of devices was subject to appropriate methods of internal monitoring, verification and validation.
- Tristel Solutions Limited confirms that the comprehensive quality assurance measures are implemented to ensure the safety, efficacy, and conformity of the procedure pack with regulatory standards.

EU Authorized Representative:

Tristel NV (SRN: BE-AR-000006771)
Smallandlaan 14 B, Antwerpen, 2660, Belgium

Approved by:

Signature:		Title:	Regulatory Affairs Specialist
Name:	Somya Singhai	Date:	29-Jan-2026