

DECLARATION OF CONFORMITY

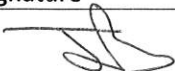
This declaration of conformity is issued under the sole responsibility of PolarSeal Tapes and Conversions Ltd in compliance to Article 19 of EU MDR 2017/745. We hereby declare that the medical device specified below meets the provision of the Annex IV of Regulation EU MDR 2017/745 for medical devices.

Validity: This declaration of conformity ceases to be valid with the issue of a new declaration of conformity or withdrawal

The declaration is based on:

Manufacturer	Polarseal Tapes and Conversions Ltd
Manufacturer Address	Guildford Road Trading Estate, Farnham, Surrey GU9 9PZ
PolarSeal SRN (Single Registration Number)	GB-MF-000029062
Authorized Representative Name/Address/SRN	MedEnvoy Global B.V. Prinses Margrietplantsoen 33 Suite 123 2595AM The Hague The Netherlands SRN - NL-AR-000024028.
Name of the Device	Ectovise C-Smile T1
Product code	CS-T1
UDI-DI	5060614870029
Intended Use	The C-Smile T1 transparent face mask is a non-sterile medical device and recommended for single shift use. Its primary purpose is for healthcare professionals, healthcare workers, first responders and other personnel to protect the patient from infection via direct breath, vapour, liquid splashes and droplets at the same time as letting their facial expressions being seen.
Classification with rule number	C-Smile T1 is classified as a Class I non-invasive, single-use, non-sterile device
Conformity assessment route	Medical Device Regulation 2017/745 in accordance with Rule 1 Annex VIII.
Harmonized Standards	Meets the splash resistance performance requirements for type IIR surgical masks (EN14683:2019+AC:2019, chapter 5.2.7). Meets the microbial cleanliness (bioburden) performance requirements for type IIR surgical masks (EN14683:2019+AC:2019, chapter 5.2.7). The filter area meets the breathability performance requirements for type IIR surgical masks (EN14683:2019+AC:2019, chapter 5.2.7). The filter area meets the bacterial filtration efficiency performance requirements for type IIR surgical masks(EN14683:2019+AC:2019, chapter 5.2.7). The panoramic window meets the EN166:2002 resistance to fogging (anti-fog) performance requirements.
Start of CE marking	February 2022

Signed for and behalf of PolarSeal Tapes and Conversions, Guildford Road Trading Estate, Farnham, Surrey, United Kingdom

Name	Position	Signature	Date (dd/mm/yyyy)
John Rich	Director		07-12-2022