


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.

The declaration is based on:

Manufacturer	Polarseal Tapes and Conversions Ltd
Manufacturer Address	Guildford Road Trading Estate, Farnham, Surrey GU9 9PZ
SRN (Single Registration Number)	NL-AR-000000116
Authorized Representative Name	EMERGO EUROPE
Authorized Representative Address	Prinsessegracht 20, 2514 AP The Hague, The Netherlands
Name of the Device	Ectovise C-Smile T1
Product code	CS-T1
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). Meets the breathability performance requirements for type IIR surgical masks (EN14683:2019+AC:2019, chapter 5.2.7). Meets the bacterial filtration efficiency performance requirements for type IIR surgical masks (EN14683:2019+AC:2019, chapter 5.2.7). Meets the EN166:2002 resistance to fogging (anti-fog) performance requirement
Start of CE marking	February 2022

Name	Position	Signature	Date (dd/mm/yyyy)
JOHN RICH	DIRECTOR		11/02/2022