


DECLARATION OF CONFORMITY (UKCA)

This declaration of conformity is issued under the sole responsibility of PolarSeal Tapes and Conversions Ltd. We hereby declare that the medical device specified below is in compliance with Directive 93/42/EEC for medical devices (Annex VII) as brought into UK law and amended 'Medical Devices Regulations 2002 (SI 2002 No 618)'.

The declaration is based on:

Manufacturer	PolarSeal Tapes and Conversions Ltd
Name and Address	Guildford Road Trading Estate, Farnham, Surrey GU9 9PZ United Kingdom
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 in accordance with Rule 1 Annex IX of Directive 93/42.
Conformity assessment route	In conformity with Directive 93/42/EEC on medical devices (Annex VII) as brought into UK law and amended 'Medical Devices Regulations 2002 (SI 2002 No 618)'
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 UKCA marking	February 2022

Name	Position	Signature	Place and Date (dd/mm/yyyy)
John Rich	Director		Farnham, United Kingdom 22-09-2022