



UE Conformity Declaration

SOGEVA Srl in quality of Manufacturer and sole responsible for medical devices sold into market with its own brand and name declares under its own responsibility that the device object of this declaration is conforming to general requirements of safety and performance requested by Encl. I of (UE) 2017/745 Norm.

Manufacturer	SOGEVA Srl – Via Pietro Nenni snc – 23801 Calolziocorte (Lecco) Italia
SRN Manufacturer number	//
Medical Device	BARRIER FILM
Basic UDI-DI	803384470BARRIERFILMUF
Class	Class I Rule 1 Encl VIII Norm (UE) 2017/745
Conformity Assesment Procedure	UE 2017/745 Rule: Encl II – Technical documentation Encl III –Post-marketing surveillance technical documentation

Any modification made to the Medical Device if not authorized by SOGEVA Srl cancels the validity of this declaration.

We declare that the device in question is sold in a non-sterile package.

We declare that the devices in question comply with the following technical standards:

- EN ISO 14971
- EN ISO 15223-1
- EN ISO 10993-1
- EN 62366

We declare that the undersigned will keep the documentation referred to in Annex I, II and III of Regulation (EU) 2017/745 available to the Competent Authority for a period of 10 years starting from the last production date of the devices in question. .

Calolziocorte (LC) - ITALY, 18.01.2022



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CODE LIST

BARRIER FILM

BARRIER FILM B	10x15cm blue color	1200 sheets/single pack
BARRIER FILM T	10x15cm transparent	1200 sheets/single pack
<i>origin of the goods</i>	<i>Made in Italy</i>	