SOGEVA Srl
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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 responsabilty 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	**IT-MF-000026322**
Medical Device	**ABSORBENT AND WATERPROOF TOWELS**
Basic UDI-DI	**803384470TOWELSMX**
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

SOGEVA s.r.l.
L'Amministratore