



Focus on health

DECLARATION OF CONFORMITY

Manufacturer	ABIGO Medical AB Vapenvägen 1, SE-696 33 Askersund, Sweden
Device classification and rule (Regulation EU 2017/745 Annex VIII)	IIb, Rule 4
SRN of the Manufacturer:	SE-MF-000000736

Basic UDI-DI: 07392130Sorbact5E2
EMDN: M040416

Intended Purpose: Sorbact® Gel Compress/Cutimed® Sorbact® Gel is intended for use in management of clean, contaminated, colonized or infected dry to exuding wounds, such as surgical wounds, traumatic wounds, burns, pressure ulcers, diabetic foot ulcers and leg ulcers. Sorbact® Gel Compress/Cutimed® Sorbact® Gel can be used on both superficial and deep wounds.

Trade and Product Name	Catalogue number (REF)
Sorbact® Gel Compress	Healthcare: 98136, 98137, 98138, 98138FR, 98139, 98180, 98181
Cutimed® Sorbact® Gel	Healthcare: 72611-20, 72611-22, 72611-24, 72611-21, 72611-23, 72611-25, 72611-26, 72611-27, 72611-28, 72611-29, 72611-31, 72611-32

Conformity assessment based on a quality management system and on assessment of technical documentation per **Annex IX Chapters I & III of Regulation (EU) 2017/745** has been performed by the following Notified Body:

Name and address	Notified Body id no	EC Certificate no and validity
Intertek Medical Notified Body AB, Torshamnsgatan 43, Box 1103, SE-164 22 Kista, Sweden	2862	28620115063-02, 28 June 2026

This declaration of conformity is issued under the sole responsibility of ABIGO Medical AB as the manufacturer. I hereby declare that the above-mentioned devices comply with **Regulation (EU) 2017/745** concerning medical devices.

Askersund 8/5-23

Place and date of issue


Fredrik Stenbäcker, Managing Director