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: 07392130Sorbact1DS
EMDN: M040416

Intended Purpose:

Healthcare: Sorbact® Compress/Cutimed® Sorbact® Swab is intended for use in management of clean, contaminated, colonized or infected exuding wounds, such as surgical wounds, traumatic wounds, pressure ulcers, diabetic foot ulcers and leg ulcers. Sorbact Compress can be used on both superficial and deep wounds.
Consumer: Sorbact® Compress is intended for use on exuding wounds such as surgical wounds and acute wounds.

Trade and Product Name	**Catalogue number (REF)**
Sorbact® Compress	Healthcare: 98110, 98111, 98124, 98125, 98128 Consumer: 98127, 98131
Cutimed® Sorbact® Swab	Healthcare: 72164-16, 72164-17, 72164-18, 72164-19, 72164-20, 72164-21, 72165-14, 72165-15, 72165-16, 72165-17, 72165-18, 72165-19, 72693-09, 72693-10

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 7 October 2022
Place and date of issue

Annika Fahlén, Regulatory Affairs & Quality Director
On behalf of Fredrik Stenbäcker, Managing Director