



Focus on health

## DECLARATION OF CONFORMITY

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

<b>Basic UDI-DI:</b> 07392130Sorbact5E2
<b>EMDN:</b> 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.

<b>Trade and Product Name</b>	<b>Catalogue number (REF)</b>
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:

<b>Name and address</b>	<b>Notified Body id no</b>	<b>EC Certificate no and validity</b>
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