



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: Cutimed Sorbact Hydro® 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. Cutimed Sorbact Hydro® can be used on both superficial and deep wounds.

Trade and Product Name	Catalogue number (REF)
Cutimed Sorbact Hydro®	Healthcare: 72611-40, 72611-41, 72611-42, 72611-44, 72611-45, 72611-46, 72611-47

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.

2024-08-12

Mölnadal, date of issue

Marie Skoglund, Regulatory Affairs Director
On behalf of Anna Arvidsson, Managing Director

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