Absorbest

EU Declaration of Conformity

Absorbest AB, Klintvägen 1, 590 39 Kisa, Sweden
Economic operator status: Manufacturer
SRN: SE-MF-000003933

Regarding product brand:	**UrgoSuperSuperabsorber**
Generic device group:	DryMax wound care family (sterile)
Basic UDI-DI for Generic device group:	735003191F650123456793F

This is to confirm that the requirements specified in the EU Medical Device Regulations 2017/745 and amendments have been fulfilled in compliance to Annex I General Safety and Performance Requirements, and by a conformity assessment procedure in accordance with Annex IX Chapters I & III – and that a technical documentation is available.

This EU Declaration of Conformity is issued under the sole responsibility of the legal manufacturer of the concerned products: Absorbest AB, Klintvägen 1, 590 39 Kisa, Sweden

This EU Declaration of Conformity is valid for the products described below, bearing MDR class IIb classification and the CE-mark NB 2862 by Intertek Medical Notified Body AB, Torshamnsgatan 43, 164 22 Kista, Sweden, through the valid MDR EC certificate number 28620148569, with expire date 2027-05-30.

UrgoSuperSuperabsorber is a superabsorbent dressing for exuding wounds.
The product is a class IIb sterile, non-invasive medical device according to MDR Annex VIII rule 4, second bullet point.

List of devices according to this DoC:

REF	Packaging size	Official product size
581020	10-pack	10 x 10 cm
581021	25-pack	10 x 10 cm
581022	50-pack	10 x 10 cm
581023	10-pack	10 x 20 cm
581024	25-pack	10 x 20 cm
581025	50-pack	10 x 20 cm
581026	10-pack	20 x 20 cm
581027	25-pack	20 x 20 cm
581028	50-pack	20 x 20 cm
581029	10-pack	20 x 30 cm

Kisa, Sweden, 2024-02-01

Hans Karlsson
Managing Director / CEO
Absorbest AB

MDR-DoC10-i