

EU Declaration of Conformity

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

Regarding product brand: **DryMax SOFT**

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.

DryMax SOFT is a superabsorbent dressing for exuding wounds.

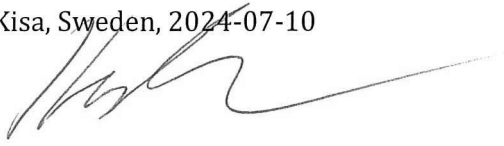
The product is a class IIb sterile, non-invasive medical device according to MDR Annex VIII rule 4, second bullet point.

List of devices according to this DoC:

REF	Official size
F60011/10	7.5x7.5 cm
F60011/25	7.5x7.5 cm
F60012/10	10 x 15 cm
F60012/25	10 x 15 cm
F60013	10 x 10 cm
F60013/3	10 x 10 cm
F60013/10	10 x 10 cm
F60013/25	10 x 10 cm
F60014/10	15 x 20 cm
F60014/25	15 x 20 cm
F60015	10 x 20 cm
F60015/3	10 x 20 cm
F60015/10	10 x 20 cm
F60015/25	10 x 20 cm

F60016/10	20 x 20 cm
F60016/25	20 x 20 cm
F60017/10	20 x 30 cm
F60017/25	20 x 30 cm
F60018/10	20 x 25 cm
F60018/25	20 x 25 cm
F60019/10	37 x 56 cm
F60121/10	15 x 15 cm
F60121/25	15 x 15 cm
F60123	12.5x12.5 cm
F60123/3	12.5x12.5 cm
F60123/10	12.5x12.5 cm
F60123/25	12.5x12.5 cm
F60125/10	5 x 5 cm

Kisa, Sweden, 2024-07-10



Hans Karlsson
Managing Director / CEO
Absorbest AB

MDR-DoC19-n