	EU Declaration of Conformity	Version Number: 01 Date: Date of Signature
	Beacon Chest Seal	

Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of Beacon Medical.

Beacon Medical
3002 Gill Street
IL 61704, Bloomington
USA
SRN: US-MF-000032370

Information on Authorised Representative:

mdi Europa GmbH
Langenhagener Str. 71
30855, Langenhagen
Germany
SRN EC Rep: DE-AR-000006218

Beacon Medical
herewith declares that the device
Beacon Chest Seal (Occlusive adhesive dressing for open chest wounds)

Basic UDI-DI: 00860006949006

Chest Seals (UMDNS-group 15704 Dressings, Occlusive)
to which this certificate refers

is in conformity with the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017.
According to rule 4 of annex VIII of Council Regulation 2017/745 (2017) the Beacon Chest Seal is a class I medical device.
The conformity assessment procedure has been performed according to Annex II, III and IV.


Validity: This declaration of conformity ceases to be valid with the issue of a new declaration of conformity or withdrawal.

List of Devices:

Product	Model	UDI-DI
Chest Seal, Non-Vent, No Gauze, 1/Pack	BCS-92590	00860006949006
Chest Seal, Non-Vent, Kit, No Gauze, 1/Pack	BCS-92590K	00860006949013
Chest Seal, Non-Vent, No Gauze, 2/Pack	BCS-92592	00860006949020
Chest Seal, Vent, No Gauze, 1/Pack	BCS-92594	00860006949037
Chest Seal, Vent, Kit, No Gauze, 1/Pack	BCS-92594K	00860006949044
Chest Seal, Vent& Non-Vent, Combination Pack, 1 of Each	BCS-92596	00860006949051
Chest Seal, Vent, No Gauze, 2/Pack	BCS-92598	00860006949068
Chest Seal, Vent, Kit, Perforated, No Gauze, 1/Pack	BCS-92598KP	00860006949075

Place, Date

1. September 2023
Name / Function

23 September 2023
mdi Europa GmbH
Langenhagener Str. 71
30855 Langenhagen - GERMANY
Phone +49 511 39 08 95 30
Fax +49 511 39 08 95 39

mdi Europa
CE-Marking Experts for Medical Devices