

EU overensstemmelseserklæring / EU-Declaration of Conformity

i henhold til artikel 19 i forordning (EU) 2017/745 om medicinsk udstyr
according to article 19 of medical device regulation (EU) 2017/745

Firmanavn / Company name:

Wulff MED TEC GmbH

SRN:

DE-MF-000010006

Vi erklærer under eget ansvar, at det/de produkt(er),
der er anført i nedenstående tabel, og som Wulff Med
Tec GmbH først markedsførte, opfylder de gældende
bestemmelser i forordning (EU) 2017/745 om
medicinsk udstyr.

Madrasser giver patienterne øget hvile- og
sovekomfort og øger dermed også patienternes
tilfredshed. Madrasser med viskoelastisk skumplast
med deres trykreducerende egenskaber forebygger
liggesår og bruges i behandling af patienter med
risiko for at udvikle liggesår.

Produktet/produkterne er blevet identificeret som
medicinsk udstyr i klasse I i henhold til regel 1 i bilag
VIII til forordning (EU) 2017/745 om medicinsk udstyr.

Adresse / Address:

Hennstedter Straße 3
25779 Fedderingen
Tyskland / Germany

We declare under sole responsibility, that the
product/s listed in the chart below which was/were
first placed on the market by Wulff Med Tec GmbH
meet/s the applicable provisions of the medical-
device-regulation (EU) 2017/745.

Mattresses can be used to improve the resting and
sleeping comfort of the patient and thereby also their
satisfaction. Mattresses with viscoelastic foams can
also be used as a pressure-reducing aid for
decubitus prophylaxis and therapy for patients at risk
of decubitus.

The product/s was/were identified as a medical
device in risk class I according to rule 1 in annex VIII
of the medical-device-regulation (EU) 2017/745.

**Grundlæggende UDI-DI
Basic UDI-DI**

40508244PW7X

**Produktnavn
Product name**

ViskoMatt 10
ViskoMatt 10 B
ViskoMatt 30
ViskoMatt 30 B
ViskoMatt 50

**Artikelnr.
Article no.**

4PW
4PW
4PW
4PW
4PW

Gyldighedsperiode / Validity period:

12.02.2025 – 11.02.2027


Melchior Meyer (Feb 11, 2025 21:25 GMT+1)

Melchior C. Meyer
(Managing Director)
(Administrerende direktør)



Fedderingen, 11.02.2025

ViskoMatt EU Declaration of Conformity_DA

Final Audit Report

2025-02-11

Created:	2025-02-11
By:	Marlena Groß (marlena.gross@wulff-med.de)
Status:	Signed
Transaction ID:	CBJCHBCAABAAgoybZBnEqafZOb0JsWYKrnhKpmzhbP_a

"ViskoMatt EU Declaration of Conformity_DA" History

-  Document created by Marlena Groß (marlena.gross@wulff-med.de)
2025-02-11 - 1:53:43 PM GMT
-  Document emailed to melchior.meyer@wulff-med.de for signature
2025-02-11 - 1:53:50 PM GMT
-  Email viewed by melchior.meyer@wulff-med.de
2025-02-11 - 8:24:54 PM GMT
-  Signer melchior.meyer@wulff-med.de entered name at signing as Melchior Meyer
2025-02-11 - 8:25:27 PM GMT
-  Document e-signed by Melchior Meyer (melchior.meyer@wulff-med.de)
Signature Date: 2025-02-11 - 8:25:29 PM GMT - Time Source: server
-  Agreement completed.
2025-02-11 - 8:25:29 PM GMT