

Attachment A



Technical Documentation Vakuform Positioning Systems

Declaration of Conformity

Chap. Rev. 1.0

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CE

Declaration of Conformity

according to annex VII of the council directive 93/42/EEC

We, the company VAKUFORM GMBH, Weiterstädter Landstrasse 13, 64291 Darmstadt, hereby declare on our own responsibility that the

Class 1 medical devices (Rule N of annex IX-93/42/EEC)

VAKUFORM Head rest (Order no. 11401)
VAKUFORM Head rest shell-shaped (Order no. 11400)
VAKUFORM Head component in u-shape (Order no. 11410)
VAKUFORM Head rest in teddy-shape (Order no. 11411)
VAKUFORM Head rest in x-shape (Order no. 11412)
VAKUFORM Forearm pad (Order no. 11430)
VAKUFORM Leg pad (Order no. 11450)
VAKUFORM Knee pad (Order no. 11460)
VAKUFORM Fibula pad (Order no. 11470)

(Products according to product description in annex A of our technical documentation)

are manufactured in accordance with the technical documentation and comply with the Essential Requirements of Medical Devices Directive 93/42/EEC (annex I). The products are labeled with the CE-Mark according to the above directive.

Darmstadt, 11.05.2016





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