activaTec®
HEALTH CARE PRODUCTS

CE - Declaration of Conformity

Directive 93/42/EEC on

Medical devices, Annex VII

The manufacturer

activaTec International GmbH & Co. KG
Braaker Bogen 7, 22145 Braak, Germany

herewith declare on his exclusive responsibility that the following product:

Product Description	Disposable surgical mask EN14683:2019 Typ IIR
Trademark	activaMask®
Device Classification	Class 1

meet all the provosions of the Council Directive 93/43/ECC, Annex VII, wich apply to it.

The technical documentation is saved at the manufacturer above.

The harmonized standards have been applied:

DIN EN 14683:2019-6	„Medical Face Masks - Requirements and Test Standards“
DIN EN ISO 14971:2012	„Medical devices - Application of risk management to medical devices“

Marienheide, August 2020

Jens Maak (General Manager)

MADE IN GERMANY

ActivaTec
International GmbH & Co. KG
Braaker Bogen 7
22145 Braak • Germany

Fon +49 (0)40 669094-60
Fax +49 (0)40 669094-79
sales@activatec.de
www.activatec.de

Bankverbindung
Postbank AG
IBAN: DE77440100460136976463
BIC: PBNKDEFF

Amstgericht Lübeck
HRA7602HL

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