



Declaration of Conformity

**Name and address
of Registered Manufacturer:**

[Redacted]
[Redacted]
[Redacted]

Product name: Disposable Medical Mask

Product type/model: S.1480-SFM (ZX-01)

We, [Redacted] herewith declare that the stated medical devices meet the transposition into national law, the provisions of Council Directive 93/42/EEC concerning medical devices; including, at 21 march 2010, the amendments by Council Directive 2007/47/EC. All supporting documentation is retained at the premises of the manufacturer. We are exclusively responsible for the declaration of conformity

Relevant EC Directive: Medical Device Directive 93/42/EEC

**European
Representative:
Address:** Caretechion GmbH
Niederrheinstr 71, 40474 Duesseldorf,
Germany,

Conformity assessment procedure: EC Declaration of Conformity (Annex VII of Directive 93/42/EEC)

Applied normative Standards : EN 14683:2019, EN ISO14971:2012, EN ISO15223-1:2016,
EN1041:2008, EN 62366-1:2015



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