

Bermedi Dent XE

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Declaration of Conformity

We,

Bermedi Medical Solutions GmbH Boelschestraße 27 12587 Berlin Germany

declare under our sole responsibility, that the product

Bermedi Dent XE

Medical product class IIa (rule 16 of annex IX Directive 93/42/EEC), UMDNS code 14-482

with the purpose

intraoral dental film for medical X-Ray Diagnostics

complies with all relevant requirements of the Directive 93/42/EEC.

Applied Standards:

- ISO 3665 Photography Intra-oral dental radiographic film Specification
- ISO 5799 Photography Direct-exposing medical and dental radiographic film/process systems -Determination of ISO speed and ISO average gradient

This Declaration of Conformity is valid until 2018-05-28.

Berlin, 2016-10-05

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