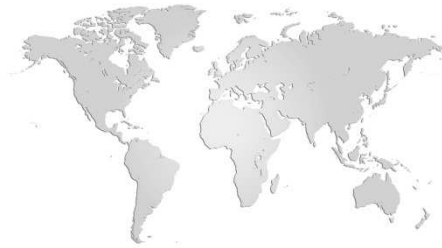


EC Design Examination Certificate



according the directive 93/42/EEC, Annex II (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies for the manufacturer

DISA Medinotec (Pty) Ltd

Stand 171, Northlands Business Park, Bush Telegraph Street, Northriding,
Johannesburg, 2169, South Africa

that the design dossier for the product(s) described in the annex complies with the requirements of the directive 93/42/EEC. This certificate is based on the result of the examination of the design dossier according to the directive 93/42/EEC Annex II.4 as documented in the report mentioned in the annex.

Product: Cape Cross NC PTCA Balloon Catheter

This certificate is valid from 2021-02-18 to 2024-03-10

Registration No.: 50923-23-J2

A handwritten signature in black ink, appearing to read 'Ruth Delbeck-Bayer', written over a circular stamp.



Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2021-02-18
Notified Body ID-number: 0124



Benannt durch/Designated by
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