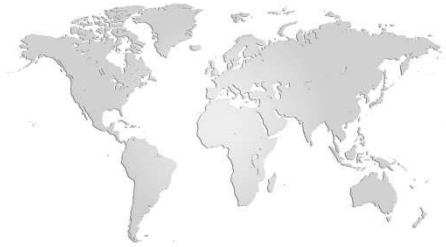
# EC Design Examination Certificate



## 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 PTCA Balloon Catheter

This certificate is valid from 2021-02-18 to 2024-01-07

Registration No.: 50923-23-F6

DEKRA Certification GmbH • DEKRA Certification • D-70565 Stuttgart, Handwerkstraße 15

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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