





Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 003973 0005 Rev. 00

Manufacturer: **Beijing Konted Medical** Technology Co., Ltd

Room 111, Building 3 No. 27 Yongwang Road

Daxing Biological Pharmaceutical Industry Base

Daxing District 102629 Beijing

PEOPLE'S REPUBLIC OF CHINA

This Confirmation Statement is only valid in combination with the following EC Certificate (MDD):

G2 003973 0002 Rev. 01

This Confirmation Statement confirms the validity of the aforementioned EC Certificate (MDD). It considers clarification of scope statements, scope reductions and changes to the manufacturer data initiated 26 May 2021 or later.

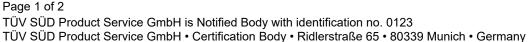
The conditions laid down in Article 120 (3) of Regulation (EU) 2017/745 on medical devices for placing devices on the market and putting into service apply.

Report No.: BJ22010802

Valid until: 2023-08-05

Christoph Dicks

Head of Certification/Notified Body Issue Date: 2023-03-24





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Product Category(ies): Pocket Ultrasound System.

Description of Change EC-Representative from Shanghai International Holding Corp. GmbH (Europe) to

SUNGO Europe B.V.

TÜV®