



Product Service

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:**

**Change EC-Representative from Shanghai
International Holding Corp. GmbH (Europe) to
SUNGO Europe B.V.**