



Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 047981 0020 Rev. 00

Manufacturer: Shanghai Chuangshi Medical Technology (Group) Co., Ltd.

No.388 Zhangliantang Road

Qingpu

201716 Shanghai

PEOPLE'S RÉPUBLIC OF CHINA

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

G2 047981 0019 Rev. 00

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. For details and confirmation statement validity see: www.tuvsud.com/ps-cert?q=cert:GCQ 047981 0020 Rev. 00

Report No.: SH2219402

Valid until: 2024-05-26

Christoph Dicks

Issue Date: 2023-04-26 Head of Certification/Notified Body

Page 1 of 2



Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 047981 0020 Rev. 00

Product Category(ies): Instant Cold Pack, Instant Hot Pack,

Hot Pack, Heat Patch

Description of

Change:

Certificate Holder changed from

" Shanghai Chuangshi Industry (Group)

Co.,Ltd "

to

" Shanghai Chuangshi Medical Technology

(Group) Co., Ltd. "