



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 090813 0010 Rev. 01

Facility(ies):

RENCARE CO., LTD.

#715/716/718, 7/F, Bldg A, No. 1003, Xin'an 6th Road, Bao'an,
518133 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

RENCARE CO., LTD.

5/F, Bldg 1, Yali Industrial Park, No.13 Tianbao Rd, Yingrenshi
Community, Shiyan Street, Bao'an, 518108 Shenzhen, PEOPLE'S
REPUBLIC OF CHINA



Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 090814 0002 Rev. 00**Manufacturer:****RENCARE CO., LTD.**

5/F, Bldg 1, Yali Industrial Park
No.13 Tianbao Rd, Yingrenshi Community
Shiyan Street
Bao'an
518108 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

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

G1 090813 0010 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. For details and confirmation statement
validity see: www.tuvsud.com/ps-cert?q=cert:GCQ_090814_0002_Rev_00

Report No.:**GZ2421101****Valid until:****2024-05-26****Issue Date:** 2024-03-08

Christoph Dicks
Head of Certification/Notified Body



Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 090814 0002 Rev. 00**Product Category(ies): Holter System, ECG Workstation and Digital Electrocardiograph****Description of Change:****1. Change of site:****Old:**

Holder: #715/716/718, 7/F, Bldg A, No. 1003, Xin'an 6th Road, Bao'an, 518133 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Facility: 5/F, Bldg 1, Yali Industrial Park, No.13 Tianbao Rd, Yingrenshi Community, Shiyao Street, Bao'an, 518108 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

New:

5/F, Bldg 1, Yali Industrial Park, No.13 Tianbao Rd, Yingrenshi Community, Shiyao Street, Bao'an, 518108 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

2. Change of scope: delete Patient Monitor