Form QAT_10-M05, version 00, effective since March 25th, 2020

Certificate of Compliance

No. 0H210121.SHM0T02

Test Report / Technical Construction File no. XMT0202101008S/LVD, XMT0202101009S/EMC

Certificate's Shanghai Huifeng Medical Instrument

Holder: Co., Ltd.

Building No.2, No.885, Qiuxing Road, Nicheng Town,

Pudong New Area, Shanghai, China

Certification ECM Mark:



Product: Model(s):

(see the following annex)

Verification to: Standard:

IEC 60601-1:2020, IEC 60601-1-2:2020

related to CE Directive(s):

2014/30/EU (Electromagnetic Compatibility)

Remark: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

2014/35/EU (Low Voltage)

Additional information and clarification about the Marking:



The manufacturer is responsible for the CE Marking process, and if necessary, must refer to a Notified Body. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

January 2021

Issuance date: 21 January 2021

Expiry date: 20 January 2026

Reviewer Technical expert Amanda Payne



Approver ECM Service Director Luca Bedonni

SHANGHAI HU

Annex I

No. 0H210121.SHM0T02

TRUMENT CO.,LTD.

Test Report / Technical Construction File no. XMT0202101008S/LVD, XMT0202101009S/EMC

Model(s):

HFP-C+E ICU, HFZ-L, HFZ-L(W), HFZ-X, HFP-C+C ICU, HFP-E+E ICU, HFP-C+S ICU, HFP-S+E ICU, HFP-S+S ICU, HFP-C ICU, HFP-E ICU, HFP-S ICU, HFP-U ICU, HFP-DQSY-1, HFP-SD90/160, HFP-SS90/160, HFP-DD90/160, HFP-DS90/160, HFP-SD160/260, HFP-SS160/260, HFP-DD240/380, HFP-DS240/380

Ente Certificazione Macchine Srl