

EU DECLARATION OF CONFORMITY

MANUFACTURER: *GRI Medical & Electronic Technology Co., Ltd.*
1805 Honggao Road
314031 Jiaxing, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

EUROPEAN REPRESENTATIVE: *Emergo Europe B.V.*
Westervoortsedijk 60,
6827 AT Arnhem,
The Netherlands

PRODUCT: *Sharp Transfer Device* (refer to see the attached 1)

CLASSIFICATION: Class I, Sterile, according to MDD93/42/EEC Annex IX, Rule 1.

CONFORMITY ASSESSMENT

ROUTE: Annex V+VIII, MDD 93/42/EEC (amended by 2007/47/EC)

Medical Device Directive: *COUNCIL DIRECTIVE 93/42/EEC*
(MDD 93/42/EEC) (amended by 2007/47/EC)

We herewith declare in our own responsibility that devices listed on above meet the transportation into national law, the provisions of the above EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

NOTIFIED BODY: *TUV SUD Product Service GmbH, Ridlerstr.65•80339 Munich, Germany*

EC CERTIFICATE: *G2S 056820 0038 Rev.04*

START OF CE-MARKING: *2013-07-01*

SIGNATURE: *Sidonia Dong* 2021/05/20

NAME POSITION: Sidonia Dong VP of RA/QA AP

Attached 1

Part #	Description
30-003	Scalpel Transfer Device_Bule_Sterile_120ea/cs
30-0003-S	Scalpel Transfer Device_Bule_Sterile_120ea/cs
30-003C	Scalpel Transfer Device_Bule_Sterile_120ea/cs
30-1000-S	Tray _Sharps Transfer_Yellow_Sterile_60ea/cs
AR-30920	Scalpel Holder_w/ securing adhesive_ Sterile_120ea/cs