

Declaration of Conformity

According to article 12, medical device directive 93/42/EEC

To whom it may concern:

Shenzhen Maiwei Biotech Co., Ltd. hereby declares that the multi-patient syringe set (Mset) and safety tube (Stube) can be safely used for contrast enhanced CT procedure in combination with high pressure injectors of the following brands: Medrad, Mallinckrodt, Liebel-Flarsheim, Nemoto, Medtron, Imaxeon and EZEM. We are liable for damages to the injector caused by our products. The following items are produced by Shenzhen Maiwei Biotech Co., Ltd., as a manufacturer within the meaning of Directive 93/42/ EEC and are validated for the use of a maximum time period of 12 hours:

12hrs dual tubing system (Mtrans) **D1L005, D1L006, D1L007, D1L008, D1L010,
D1L011, D1L012, D1L013**

dual Mset (12hrs syringes in conjunction with dual Mtrans) **A03105, A03112, B04105, B04109, B04111,
B04112, C07105, C07112, D02105, D02109,
D02111, D02112, F02105, F02112**

This 12 hours validation requires the use of above products in combination with one of the following single-use patient lines with non return check valve(s):

Safety tubes with 2 checkvalves **S0L010, S0L012, S0L014, S0L153 ,S0L020, S0L021,
S0L022, S0L024, S0L026, S0L028, S0L040, S0L042,
S0L044**

The hygienic safety from the Mset, Mtrans and Stube were tested as part of bacteriological and virological studies for no more than 12 Hours usage in laboratory.

Signature 
Name : Chen Zhiqiu
Title : General Manager
Shenzhen Maiwei Biotech Co., Ltd.