

## **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,  
D1L105, D1L106, D1L107, D1L108,  
D1L110, D1L111, D1L112, D1L113**

Dual Mset (12hrs syringes in conjunction with dual Mtrans)

**A03105, A03112, B04105, B04109,  
B04111, B04112, C07105, C07112,  
D02105, D02109, D02111, D02112,  
F02105, F02112**

12hrs Single Syringes (Without Mtrans)


**A03118, B01118, C01118, C02118,  
D01118, F01118, A01318, A02318,  
B01318, C01318, D01318, F01318**

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, S0L032, S0L040,  
S0L042, S0L044, S0L110, S0L112,  
S0L114, S0L155, S0L120, S0L121,  
S0L122, S0L124, S0L126, S0L128,  
S0L132, S0L140, S0L142, S0L144

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 : Zhiqiu Chen  
Title : General Manager  
Date : 2021.5.24  
Valid Until : 2022-11-16  
Shenzhen Maiwei Biotech Co., Ltd.

