

EU Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

Shanghai MediWorks Precision Instruments Co.,
Ltd.

No.7, MingPu Phase II, No.3279 SanLu Road,
MinHang District, 201100, Shanghai, China
SRN number: CN-MF-000004251

CMC Medical Devices & Drugs SL
C/ Horacio Lengo

N18, Málaga, 29006, Spain

SRN number: ES-AR-000000293

We, the manufacturer, herewith declare under our sole responsibility that above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on medical (MDR). All supporting documentations are retained under the premises of the manufacturer.

Surgical Microscopes

(Model/Type: SM610/SM620/SM622C/SM625D/SM626M/SM628S/SM623D/SM629F)

meet the provisions of EU-REGULATION 2017/745 which apply to them.

Intended Use: Surgical microscope is mainly used for magnifying details of the surgical area during non-ophthalmic surgical procedures.

The Basic UDI-DI of products are as follows:

69450875SurgicalMicrosFH

Conformity Assessment Route: CHAPTER V SECTION 2 Art.52 (7) Regulation (EU) 2017/745 on medical devices

The medical device has been assigned to RULE 10 (Device class: class I) according to Annex VIII of the EU-REGULATION 2017/745. It bears the mark



following the procedure relating to the EC Declaration of Conformity set out in Annex II of EU-REGULATION 2017/745.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Shanghai MediWorks Precision Instruments Co., Ltd.

Address: No.7, MingPu Phase II, No.3279 SanLu Road, MinHang District, Shanghai, China

Shanghai, March 12, 2015

Place, date



Zhan Weida, Vice President/PRRC

Legally binding signature, Function