

## **DECLARATION OF CONFORMITY** TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

MANUFACTURER:

Edan Instruments, Inc.

#15 Jinhui Road, Jinsha Community, Kengzi Sub-District,

Pingshan District, 518122 Shenzhen, P.R.China

**EUROPEAN REPRESENTATIVE:** 

Shanghai International Holding Corp. GmbH (Europe)

Eiffestrasse 80 D-20537 Hamburg Germany

PRODUCT/MODEL:

Trolley (For medical use) / MT-201, MT-201(S), MT-

801. MT-810

The accessories are used together with the product

UMDN [NAME/CODE]: Carts, Instrument/10641

CLASSIFICATION:

Class I , Rule 1 According To Annex IX of the MDD

CONFORMITY ASSESSMENT ROUTE: Annex VII

WE, EDAN INSTRUMENTS, INC., HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCT(S) MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 INCLUDING AMENDMENTS BY DIRECTIVE 2007/47/EC.

ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER. STANDARDS APPLIED: EN 60601-1:2006+A1:2013, EN 60601-1-2:2007/AC: 2010, EN ISO

14971:2012, EN ISO 15223-1:2016, EN 1041:2008+A1:2013, EN ISO 780:2015

NOTIFIED BODY:

TÜV SÜD PRODUCT SERVICE GMBH

RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER

START OF CE-MARKING:

2020.12.16

PLACE, DATE OF ISSUE:

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SIGNATURE:

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MANAGEMENT REPRESENTATIVE