Luanayed

Statement of EUDAMED Product Registration

This statement is issued under the sole responsibility of Luana Med. B.V., European Authorized Representative with SRN NL-AR-000002750, located at Weena-zuid 130, 3012NC Rotterdam, Netherlands, and explicitly defined per Article 11 of Regulation (EU) 2017/745 for the following product(s):

Manufacturer:

Machan International Co., Ltd.

Address:

No. 352, TA MA RD., WAIPU DIST.,

TAICHUNG CITY 438, TAIWAN

SRN:

TW-MF-000018393

Device (Products) Name:

Mobile / fixed screen device

Mobile equipment cabinet

Technical Documents and Version:

471024325FS01-FS063A, V1.2

471024324MED01-MED18YA, V1.2

The aforementioned Technical Document(s) have been verified by the Manufacturer's European Authorized Representative, Luana Med. B.V., according to Article 11. 3. (a), (b), and (c) of Regulation (EU) 2017/745 pertaining to medical devices (MDR), thus Device(s) have been registered on EUDAMED.

Signature

Name

Position

Malta Chang

Director of Regulatory Affairs

Place and Date of Issue Tordam

2 May 05