



# DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## EU Representative

SUNGO Europe B.V.  
Olympisch Stadion 24, 1076DE Amsterdam,  
Netherlands  
SRN: NL-AR-000000247

## Conformity Assessment

**Conformity Assessment Procedure**  
Annex II+III of Regulation (EU) 2017/745

**Applicable Standards**  
EN ISO 14971: 2019  
EN ISO 15223-1: 2016  
EN 1041:2008+A1:2013  
ISO 10993-1: 2018  
EN ISO 10993-5: 2009  
EN ISO 10993-10: 2013

### Remark

*The declaration of conformity is valid in connection with the release technical document CE/MDR-MT-05.*  
*All the supporting documentation is retained at the premises of the manufacturer.*  
*The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.*

## Manufacturer

**Name:** HEFEI MT MEDICAL CO., LTD.  
**Address:** Shangze Business Center, Economic Development Zone, Hefei, Anhui, China.

## Product Information

**Name:** Medical Cabinet  
**Model:** See Annex  
**GMDN:** 10531  
**Basic UDI-DI:** 697885897mct006VW  
**Classification:** Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

## Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature:  Date: 2 June, 2021



Position: GM

Place: Anhui/China

## Annex

| Product Name    | Model                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | GMDN  | Basic UDI-DI          |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|-----------------------|
| Medical Cabinet | C1,C2,C3,C4,C5,C6,C7,C8,C9,C-02,CC-04,CC-03,<br>CC-05,CC-01,CC-11,CC-06,CC-07,CC-08,CC-09,CC-10,<br>C55,C57,C56,C58,C13,C13-1,C13-2,C13-3,C13-4,C13-5,<br>C13-6,C13-7,C13-8,C13-9,C13-10,C13-11,C13-12,C12,<br>C12-2,C14,C15,C16,C17,C18,C19,C20,C21,C22,C23,C24,<br>C25,C26,C27,C28,C29,C30,C31,C32,C33,C34,C35,C36,C37,<br>C38,C38-1,C39,C40,C41,C42,C43,C44,C45,C46,C47,C48,<br>C49,C50,C51,C52,C53,C54,C60,C61,C62,C63,C64,C65,C66,<br>C67,C68,C69,C70,G01,G02,G03,G04,G05,G06G07,G08,G09,<br>G10,G11,G12,G13,G14,G15,G16,G17,G18,G19,G20 | 10531 | 697885897<br>mct006VW |

Signature:

Position: GM

Date: 2 June, 2021

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