



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.

**Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The
Netherlands**

SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure

Annex II+III of Regulation (EU) 2017/745

Applicable Standards

EN ISO 14971: 2019/A11:2021

ISO 15223-1: 2021/Amd 1:2025

EN ISO 20417:2021

EN ISO 10993-1: 2020

EN ISO 10993-5: 2009/A11:2025

EN ISO 10993-10: 2023

EN ISO 10993-23: 2021

Remark

*The declaration of conformity is valid in connection
with the release technical document
MDR-TCF-002.*

*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.*

File No.: MDR-TCF-002-08

Manufacturer

Name: WUYI COMON MEDICAL APPLIANCES CO.,
LTD

Address: Juhua Road , Baihuashan Industry Zone ,
Wuyi County, Jinhua City , Zhejiang Province

SRN: CN-MF-000034494

Product Information

Name: RAISED TOILET SEAT

Model: See Annex

EMDN: Y091215

Basic UDI-DI: 697628980RTS00124

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



Position: GM

Date: 2025/8/5

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Place: Zhejiang/China

Annex

Name	Model
Raised Toilet seat	6001-2,6001-4,6001-6,6001L-2,6001L-4,6001L-6,6002-2,6002-4,6002-6,6002L-2,6002L-4,6002L-6,6003,6004,6005,6006,6007-2,6007-4,6008-2,6008-4,6008-6,6008L-2,6008L-4,6008L-6,6009-2,6009-4,6009-6,6010,6011,6012,6012L,6013,6013L,6014,6014L,6015,6016,6017,6018,6019,6020,6021,6022,6023,6024,6025,6026,6027,6028,6029,6029L,6030,6031,6032,6033,6034,6035,6036,6037,6038,6039,6040,6041,6042,6043,6044,6045,6046,6047,6048,6049,6050,6051,6052,6053,6054,6055,6056,6057,6058,6059,6060,6061,6062,6063,6064,6065,6066,6067,6068,6069,6070,6071,6072,6073,6074,6075,6076,6077,6078,6079,6080,6081,6082,6083,6084,6085,6086,6087,6088,6089,6090,6091,6092,6093,6094,6095,6096,6097,6098,6099,6100,6101,6102,6103,6104,6105,6106,6107,6108,6109,6110,6111,6112,6113,6114

