



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: 2021
EN ISO 20417:2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
EN ISO 11334-1:2007
EN ISO 11334-4:1999

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Y1203-01.

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: NINGBO GAOBO SPORTS CO., LTD
Address: Dali, Shenzhen Town, Ninghai County, Ningbo City, China
SRN:

Product Information

Name: Cane & crutches
Model: See Annex
EMDN: Y1203
GMDN: 31115/31113/31112/31116
Basic UDI: 697584351cane001XJ
UDI-DI: 16975843510010
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:

Position: GM

Place: Ningbo/China



Annex

Product Name	Model
Cane&crutches	GB-801, GB-802, GB-803, GB-804, GB-805, GB-806, GB-807, GB-808, GB-809, GB-810
	GB-811, GB-812, GB-813, GB-814, GB-815, GB-816, GB-817, GB-818, GB-819, GB-820
	GB-821, GB-822, GB-823, GB-824, GB-825, GB-826, GB-827, GB-828, GB-829, GB-830
	GB-831, GB-832, GB-833, GB-834, GB-835, GB-836, GB-837, GB-838, GB-839, GB-840
	GB-841, GB-842, GB-843, GB-844, GB-845, GB-846, GB-847, GB-848, GB-849, GB-850
	GB-851, GB-852, GB-853, GB-854, GB-855, GB-856, GB-857, GB-858, GB-859, GB-860
	GB-861, GB-862, GB-863, GB-864, GB-865, GB-866, GB-867, GB-868, GB-869, GB-870
	GB-705, GB-706, GB-707, GB-708, GB-709, GB-710, GB-712, GB-713, GB-714, GB-715
	GB-8031, GB-806a, GB-830a, GB-819a, GB-8031a, GB-8070, GB-8020, GB-8060

