DECLARATION OF CONFORMITY according to

Medical Device Regulation 2017/745

according to Annex IV

Manufacturer name an adress & SRN	Authorized EC Representative name and contact
Yuyao Hairui Medical Device CO., LTD. No. 18, Beixing Toad, Mazhu Town 315450 Yuyao City, Zhejiang P.R. China	MedPath GmbH Mies-van-der-Rohe-Str. 8 80807 München GERMANY
SRN: CN-MF-000041902	SRN: DE-AR-000000087

Hereby we declare under our responsibility that the following listed medical devices meet all applicable basic safety and performance requirements according to Annex I of Regualtion (EU) 2017/745 (MDR).

The Confomity Assessment Procedure has been performed self-dependent according to Art. 52 VII and Art. 19 of the Regulation (EU) 2017/745, for class I medical devices. We confirm that we have established and maintain a technical documentation according to annex II and III of the Regulation (EU) 2017/745.

Basis UDI-DI	man.reference	Description
N/A	2.4.5	double swivel connector
N/A	2.4.3.1.X.X.X	oxygen tubing series
N/A	1.8.1.29.X	connector
N/A	2.4.6	water trap
N/A	2.4.3.3.5 CHX0	oxygen catheter series
N/A	1.8.1.29.1	Adapter for humidifier
N/A	2.4.X	ETCO2 sampling line, male to male series
N/A	1141-CPAP	Connector CPAP 22F/15/22 mm
N/A	114-OCSA	Oxygen Disposable Sets
N/A	1148-HCT	Connector-Tube for Humidifiers

Device classification: according to annex VIII rule 1 I

Intended Purpose:

The products are used for oxygen therapy.

Applied harmonised standards, national standards or other normative documents

regulation (EU) 2017/745
DIN EN ISO 13485:2016

Harmonised certification: ISO 13485:2016 Certificate Number SX 2121387-1

Expiry Date: 25-06-2026

name and signature of authorized company officer

2024-04-04