

Declaration of Conformity
According to Medical Device Directive (MDD) 93/42/EEC

Device trade name and model/order number

Description	DROH article code	Manufacturer REF
See attached list		

Device classification

II a

Manufacturer name and address

ZHEJIANG MEDUNION HEALTHCARE GROUP CO., LTD.
No. 31 Yaohang Street

315010 Ningbo
China

Notified Body name and ID number

TÜV SÜD Product Service GmbH
Ridlerstr. 65
80339 Munich
Germany

 0123

CE certificate number

G2 092925 0002 Rev. 02

Date CE Marking was first applied

25.09.2018

Expiry Date of CE certificate

17.05.2021

Authorized EC Representative contact information

MedPath GmbH
Mies-van-der-Rohe-Str. 8
80807 München
Germany

Route to compliance

Annex V

Standards applied

(Besides harmonized standards: http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/medical-devices/index_en.htm)

浙江美联医疗用品股份有限公司
ZHEJIANG MEDUNION HEALTHCARE GROUP CO., LTD



Name and signature of authorized company officer

Description	DROH article code	Manufacturer REF
adult cannula with 2.1 mt sure flow tubing	02-031-E	2.4.3.2.1.2
adult cannula with ear loops	02-035-E	2.4.3.2.6
adult oxygen mask without supply tubing	02-040-E	2.4.1.1.1
adult oxygen mask elongated wit 7 ft. Tubing	02-050-E	2.4.1.1.5
adult oxygen mask with 7 ft. Sure flow tubing	02-051-E	2.4.1.1.4
adult oxygen mask elongated - non rebreathing series	02-05X-E	2.4.1.2.X
aerosol kit with nebulizer, aerosol mask series	02-06X-XX	2.4.1.3.5
pediatric oxygen mask with 7 ft. Supply tubing	02-080-E	2.4.1.1.3
infant oxygen mask with 2.1m tubing	02-081-E	2.4.1.1.2
pediatric oxygen mask, elongated - non rebreath	02-085-E	2.4.1.2.3
pediatric aerosol kit with nebulizer series	02-090-E	2.4.1.3.X
double swivel connector	02-1220-E	2.4.5
oxygen tubing series	02-1300-30-E	2.4.3.1.X.X.X
oxygen tubing with standard connector series	02-1310-E	2.4.3.1.X
adult clear cannula with enhanced reservoir face	02-1600HF-E	2.4.3.2.8
oxygen quick connector	02-145-B	PO-85210
DISS and nipple christmas tree hose barb, green	02-211-B	PO-85130
oxygen nipple connector green	02-212	PO-85120
adapter for humidifier	02-213-B	PO-85240
water trap	02-215-E	2.4.6
hyperventilation mask with reservoir bag	02-310-E	2.4.1.2.4
oxygen catheter series	02-51X-W	2.4.3.3.5 CH X0
adult cannula with 2.1m, curved prong	021-BUDE-031	2.4.3.2.1.4
adult oxygen mask elongated with 7 ft. Tubing	021-BUDE-050	2.4.1.1.5
adult oxygen mask elongated - non rebreathing	021-BUDE-055	2.4.1.2.2
adult cannula sure flow tubing series	021-EKNE-XX0	2.4.3.2.1.X
pediatric clear cannula with 2.1m supply tube	021-SKNE-200	2.4.3.2.11
infant cannula with 7 ft. Supply tube	021-SSNE-100	2.4.3.2.10
adult silicone cannula series	021-SNFM-1X0	1.14.1.X
cannula with tube and luer lock connector series	022-EKLE-XX0	2.4.3.2.9.X
silicon supply oxygen tubing series	024-SSNE-0XX	1.14.4.X
350 cc bubble humidifier	026-EHFE-350	2.4.7
ETCO2 sampling lines, male to male series	093-MMLG-XXX	2.4.X
PVC suction tube series	121-ERPZ-0XXX	1.5.15.X