

Declaration of Conformity

Doc.No.: YL/CE06-04

Manufacturer:	YIWU ORI-POWER MEDTECH CO.,LTD.
European Representative:	MedPath GmbH Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany
Product Name	Face masks
Model Number:	OP1510
UMDNS-Code:	12447

Classification (MDD, Annex IX): Class I Non Sterile Rule 1

Conformity Assessment Route: **Annex VII**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

#86 Xiahe Rd., Beiyuan Industrial Park,322000,Yiwu, PEOPLE'S REPUBLIC OF CHINA

Manufacturer takes full responsibility of the content of Declaration of Conformity.

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC



Harmonized Standards:

EN ISO13485:2016 EN ISO15223-1:2016

Signature: *Amy Chen*

Position:sales manager

Place& Date: #86 Xiahe Rd., Beiyuan Industrial Park,322000,Yiwu, PEOPLE'S

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义乌源力医疗科技有限公司
YIWU ORI-POWER MEDTECH CO.,LTD