EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: /
Name and address of the manufacturer: **Jiangxi Yikang Medical Instrument Group Co., LTD;**
NO.188 LiduAihua Ave.,Jinxian County,Nanchang,Jiangxi,China.

Nom et adresse du fabricant: /
Nome e indirizzo del fabbricante:

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that /
Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: /
the medical device: **Face Masks For Single Use (Model: S/M/L)**

le dispositif médical: /
il dispositivo medico:
GMDN Code: **35177**
der Klasse: /
of class: **I sterile, Rule 1**
de la classe: /
di classe:

nach Anhang IX der Richtlinie 93/42/EWG / according to annex IX of directive 93/42/EEC /
selon l'annexe IX de la directive 93/42/CEE / secondo l'allegato IX della direttiva 93/42/CEE

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 93/42/EWG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll". /

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 93/42/CEE et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l'inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 93/42/CEE e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il "rapporto di ispezione finale" del prodotto.

Konformitätsbewertungsverfahren: /
Conformity assessment procedure: **Annex II, excluding Section 4**
Procédure d'évaluation de la conformité: /
Procedura di valutazione della conformità:

Registrier-Nr.: /
Registration No.: **HD 60147620 0001**
N°d'enregistrement: /
Numero di registrazione:

Benannte Stelle: /
Notified Body: /
Organisme notifié: /
Organismo notificato:

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Deutschland
CE 0197

NanChang/10th.05,2020
Ort, Datum / Place, date /
Lieu, date / Luogo, data

/ Management representative
Name und Funktion / Name and function /
Nom et fonction / Nome e funzione

Appendix: Harmonized standards list

No.	Document number	Version number	Name of Document
1.	EN ISO13485	2016	Quality system—Medical devices-Particular requirements
2.	EN ISO14971	2012	Medical Device –Risk Analysis—Part 1: the Application of risk analysis
3.	EN ISO10993-1	2009/AC:2010	Biological Evaluation of Medical Device-Part 1: Evaluation and testing
4.	EN ISO10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
5.	EN ISO 10993-7	2008	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
6.	EN ISO10993-10	2010	Biological Evaluation of Medical Device-Part 10:stimulation and allergic reaction
7.	EN ISO 15223-1	2016	Graphic Symbols for use in the labeling of medical device
8.	EN 1041	2008+A1:2013	Terminology, Symbols and Information with Medical Devices; Information supplied by the manufacturer with medical devices
9.	EN ISO 11607-1	2017	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
10.	EN ISO 11607-2	2017	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
11.	EN 868-1	1997	Packing Materials for Sterilization of Wrapped Goods-Part 1:Genenal Requirements and Requirements for the Validation of Packing for Terminally Sterilized Device
12.	EN ISO11737-1	2018	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
13.	EN ISO11737-2	2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
14.	EN ISO11135	2014	Sterilization of medical health care product -conformation and routine control requirements
15.	EN 14683	2019	Surgical masks-Requirements and test methods
16.	EN 556-1	2001/AC:2006	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
17.	EN 556-2	2015	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 2: Requirements for aseptically processed medical devices
18.	EN 62366-1	2015	Medical devices - Application of usability engineering to medical devices IEC 62366:2008