BETTER AG

Top Qualität zu Herstellerpreisen

Einweg-Clipkappe

CE-zertifiziert

S Standard Line

C Comfort Line

TÜVRheinland®

CE

100 Kappen pro Box | **Einweg-Clipkappe** | 2000 Kappen pro Karton

DE: + 49 (0) 30 62 93 34 20
CH: + 41 71 58 80 248

Shop: www.OdemShop.de
E-Mail: info@OdemShop.de

Standard Line

Spezifikation:
21 Zoll, 10g
Einzelne Sehne
Blau

Verpackungsschachtel:
100 Stück
20 cm x 8,5 cm x 18 cm

Verpackungskarton:
2000 Stück
45 cm x 44 cm x 38 cm
G.W.: 7,7 KG
NETTOGEWICHT: 6,4 KG

Comfort Line

Spezifikation:
21 Zoll, 12g
Doppelsehne
Blau

Verpackungsschachtel:
100 Stück
20 cm x 8,5 cm x 20 cm

Verpackungskarton:
2000 Stück
45 cm x 44 cm x 41 cm
G.W.: 8,5 KG
NETTOGEWICHT: 7,2 KG

Odem

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60133273 0001

Report No.: 15085900 005

Manufacturer:

Xiantao Xingrong Protective
Products Co., Ltd.
No. 46, East of Pengchang Road,
433018 Xiantao, Hubei
China

Products:

Aspects of manufacture concerned with securing and maintaining sterile conditions of Face Masks, Surgical Gowns, Non-woven Caps, Non-woven Shoe Covers, Plastic Shoe Covers, Coveralls

Replaces Approval, Registration No.: DD 60104282 0001

Expiry Date: 2023-12-05

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2018-12-06

Date: 2018-12-06

Notified Body
TÜV Rheinland LGA Products GmbH
TÜVRheinland
III
Zertifizierungsstelle
Herbert Zhong

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Registration Notification

Reference Number: JH-ERA-MDR-21306V00
Effective Period: 2021.11.27-2022.11.26

This notification will be automatically void if the Notification is rejected by the EU Authorities or upon termination of the EAR.

This is notice that, According to Medical Device Regulation (EU) 2017/745(MDR), we accepted the appointment to be the Authorized European Representative for products which listed in the attached agreement between below manufacturer and Luxus Lebenswelt GmbH.

Manufacturer: Xiantao Xingrong Protective Products Co.,Ltd.

Address: NO.46 East of Pengchang Road,Xiantao,Hubei,China

The Manufacturer declared that the Medical Device complies with de Directive including all essential requirements.
According to Medical Device Regulation (EU) 2017/745(MDR), the European Databank on Medical Devices (EUDAMED) is established as of May 1, 2011, the German Competent Authority is notified of the Manufacturer's Medical Devices and has allocated registration numbers shown in:

Disposable medical mask, UMDN code: 15-230
Registration Number: DE/CA20/00182956

Where the manufacturer affixes the CE marking to the product listed, they must ensure that all the requirements of the appropriate EU directive(s) and standards have and continue to be met.

For and on behalf of

LUXUS LEBENSWELT GMBH
Kochstr.1, 47877 Willich, Germany

Only used for EU Representative Agreements

Luxus Lebenswelt GmbH
Kochstr. 1, 47877, Willich, Germany
info.m@luxuslw.de

TÜVRheinland®

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2077355-1

Organization: Xiantao Xingrong Protective Products Co., Ltd.
No. 46, East of Pengchang Road
Xiantao
433018 Hubei
P.R. China

Scope: Manufacture and Distribution of Face Masks, Surgical Gowns, Non-woven Caps, Nonwoven Shoe Covers, Plastic Shoe Covers, Coveralls

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 244376774-200
Effective date: 2022-04-08
Expiry date: 2024-12-05
Issue date: 2022-04-08

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

	Xiantao XingRong Protective Products Co., Ltd.			
	Doc. No.	XR/CE-09-01	Ver.	A/0
	Doc. Name	EC Declaration of Conformity	Effective date	2022-01-07

EC Declaration of Conformity

Manufacturer:

Name: Xiantao XingRong Protective Products Co., Ltd.
Address: No.46 Pengchang Ave, Xiantao City, Hubei Province, P.R. China
Tel/Fax: 0728-2613199/0728-2611166
SRN: CN-MF-000020687
whose single Authorized Representative:

Name: Luxus Lebenswelt GmbH
Address: Kocthstr.1 47877,Willich,Germany
Tel/Fax: 0049-1715605732
SRN: DE-AR-000005110

We, the manufacturer, herewith declare that the products

Product Name: Disposable Cap, Non-woven Cap
UMDNS CODE: 16081
BASIC UDI-DI: 697511781XRCA004XB

meet the provisions of Regulation (EU) 2017/745.
The medical device has been assigned to Class Ⅰ according to Rule1, Annex Ⅷ of the Regulation (EU) 2017/745. It bears the mark

CE

The product concerned has been manufactured under a quality management system according to Annex Ⅸ of Regulation (EU) 2017/745.
This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark.
The above mentioned declaration of conformity is exclusively under the responsibility of
Company Name: **Xiantao XingRong Protective Products Co., Ltd.**
Company Address: **No.46 Pengchang Ave, Xiantao City, Hubei Province, P.R. China**

20th, June, 2022
Place, Date

Si Xiang Liu
Legally binding signature, Function

XIANTAO XINGRONG PROTECTIVE PRODUCTS CO., LTD