By Royal Charter

EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 731449 R000

Manufacturer: Chongqing COE Display Technology Co., Ltd.

Address:
No.3, Tonggui Avenue
Yufengshan Town
Yubei District
Chongqing
401125
China

Single Registration Number: Not Available

EU Authorised Representative: Luxus Lebenswelt GmbH

Address:
Kochstr. 1
Willich
47877
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex XI part A, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb devices an additional Annex X certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2020-08-25** Date: **2020-08-25** Expiry Date: **2025-08-24**

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Device Schedule: Class III and Class IIb devices

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Disposable Medical Mask	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	

First Issued: **2020-08-25** Date: **2020-08-25** Expiry Date: **2025-08-24**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference number	Action
Current	3249933	First Issue.

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