



DECLARATION OF CONFORMITY

According to REGULATION (EU) 2017/745 -Article 19, Annex II and Annex III.

Manufacturer:

Company name: Nanjing Jusha Display Technology Co., Ltd.

Address: 8A, Block 1, Nanjing International Service Outsourcing Mansion No.301, Hanzhongmen Street, Nanjing City, Jiangsu Province, 210036 China

Tel: +86 025 8330 5050

E-mail: international@jusha.com.cn

SRN: CN-MF-000018396

Whose Authorized Representative:

Name: Lotus NL B.V.

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

E-mail: peter@lotusnl.com

We, the manufacturer, herewith declare that the device covered by the present EU declaration is in conformity with the (EU) MDR 2017/745.

Product Name	LCD Monitor		
Model	WCU2416, WCU2416-C, CP610, CP620G, C270G, M260G, M270G, C350G, M350G, C450G, C610G, C620G, C630G, JUSHA-CR22, CR240G, E190DHG, E190CG, E240AG, E260A, JUSHA-M53, M550G, C810G, S8420, JUSHA-C61, R190, R193, E240BG, E240CG, R241M, E310AG, E320AG, C1210G, S5810, E270AG, E270UAG, E550DG, C810G, C660G, C510G.		
Intend use	LCD Monitor is used to display surgical images in an endoscopic surgical environment. LCD Monitor is used in diagnostic radiology equipment such as PACS, CR, DR, CT, and MR to display the images diagnostic part.		
CND code	Z11900880	Basic UDI-DI	/
Classification and rule	I, rule 13	Conformity Assessment Route	Article 19, Annex II and Annex IX

Applicable Standards and CS:

ISO 13485:2016

IEC 60601-1: 2012

ISO 14971:2019

EN 1041:2008

IEC 60601-1-2:2014

EN 15223-1:2016

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the REGULATION (EU) 2017/745. We agree to develop, implement and maintain a documented post-production monitoring process

Signed:

Date: July 6, 2022

Place: Jiangsu, China

Name of authorized signatory: Wang Wei

Position held in the company: General Manager

Nanjing Jusha Display Technology Co., Ltd.