Declaration of Conformity

Manufacturer	
Name and address:	Ningbo Advan Electrical Co., Ltd
Contact information:	Industrial Development Zone, Fuhai Town, 315332 Cixi City, Ningbo, Zhejiang Province PEOPLE'S REPUBLIC OF CHINA
SRN:	CN-MF-000018731
Trademark:	
European Authorized Representative	
Company Name	CMC Medical Devices & Drugs S.L.
Address	C/Horacio Lengo no 18, CP 29006, Málaga, Spain
Contact	Manuel Mateos
SRN:	ES-AR-000000293
E-mail	info@cmcmedicaldevices.com
Notify Body	
Name:	TÜV SÜD Product Service GmbH Certification Body
Address:	Ridlerstraße 65 80339 München
Country:	Germany
Notified Body Identification Number:	CE 0123
（EC） Certificate(s)	G26 057924 0020 Rev.00
Expire date of the Certificate	2031-07-27
Device	
Device Name:	Disposable skin stapler
EMDN Code:	H02010101 SKIN STAPLERS, SINGLE-USE
Basic UDI-DI:	69448757SUF0012N
Model and specification:	F-W contains: F-35W, F-35WB, F-35WC, F-35WE,F-35WO, F-35WN, F-35WNA, F-35WNB, F-35WNC, F-35WND,F-35WNE,F-35WNF, F-35WL, F-35WBL, F-35WCL, F-35WEL,F-35WOL, F-35WNL, F-35WNAL, F-35WNBL, F-35WNCL, F-35WNDL,F-35WNEL,F-35WNFL. F-R contains: F-35R, F-35RB, F-35RC, F-35RE, F-35RO, F-35RN, F-35RNA, F-35RNB, F-35RNC, F-35RND, F-35RNE, F-35RNF, F-35RL, F-35RBL, F-35RCL, F-35REL, F-35ROL, F-35RNL, F-35RNAL, F-35RNBL, F-35RNCL, F-35RNDL, F-35RNEL, F-35RNFL.
Intended use:	Disposable skin stapler are intended to be used for skin closure in surgical operations.
Risk of classification:	Class IIa, Rule: According to Rule 7, Annex VIII, Chapter III of Medical Device Regulation (EU)2017/745
Conformity Assessment Procedure:	Annex XI part A of Medical Device Regulation (EU)2017/745
Technical Document No.	ADV/CE-MDR-01,Version A/2

We confirm our product can meet the requirement of Medical Device Regulation and the following harmonized standards:

EN ISO 13485:2016, EN ISO 15223-1:2021, EN ISO 20417-2021, EN ISO 14971:2019, EN ISO 11607-1:2020, EN ISO 11607-2:2020,EN ISO 14644-1:2015, EN ISO 14644-2:2015, ISO5832-1:2016, EN ISO 10993-1:2009, EN ISO 10993-5:2021, EN ISO 10996-6:2016, EN ISO 10993-10:2023, EN ISO 10993-7:2008, EN ISO 10993-23:2023, EN ISO 10993-11:2018, EN ISO 10993-12:2020, EN ISO 7153-1:2016, EN ISO 11737-1:2018, EN ISO 11737-2:2020, ISO EN 11135:2014, ASTM F1980-16:2016, ASTMD4169-16:2016

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation

(EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

Signature/ Position: ：  **Place/Position: Cixi/ PRRC** **Date：2026.07.28**