JIANGSU YADA TECHNOLOGY GROUP CO.,LTD
江苏亚达科技集团有限公司

EU DECLARATION OF CONFORMITY

Name and address of the manufacturer: /	Jiangsu Yada Technology Group Co., Ltd. Yada Road, Touqiao Town, Guangling District, Yangzhou, 225109 Jiangsu, P.R. China SRN:CN-MF-000014686
Registered trade name or mark:/	Disposable Medical Forceps
EC Authorized Representative:/	Share info GmbH Am Schulzentrum 12, 41564 Kaarst, Germany SRN: DE-AR-000005132

We declare under our sole responsibility that

Name of the medical device: /	Disposable Medical Forceps Model: YD-PF001, YD-PF002, YD-PF003, YD-PF004, YD-PF005, YD-SF001, YD-SF002, YD-MF101, YD-MF102, YD-MF103, YD-MF104, YD-MF201, YD-MF202
Product code:/	EMDN code: V9099
Intended purpose：/	Disposable medical Forceps are used by medical staff to pick up cotton balls or gauze during operation. A Hand-held manual instrument designed primarily for non-dedicated grasping of devices, sponges and dressing during a procedure.
Basic UDI-DI:/	69567478YD-DMFP6R, 69567478YD-DMFS6X, 69567478YD-DMFMLG3
CS reference: /	NONE
of class: /	Class I, according to Rule 1, Classification rules of Regulation (EU) 2017/745

According to annex VIII of Regulation (EU) 2017/745 /

Conformity assessment procedure:	According to Annex IV EU conformity declaration and Annex II Technical Documentation of Regulation (EU) 2017/745.

Meets the provisions of the Regulation (EU) 2017/745 and other relevant Union legislation which apply to it. The declaration is valid in connection with the “final inspection report” of the device.

No.	Title	
1.	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
2.	MDR 2017/745/EU	Medical Device Regulation
3.	EN ISO 15223-1:2021	Medical devices - symbols to be used with medical device labels, labelling and information to be supplied - part 1: general requirements
4.	EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer

No.	Title	
5.	EN ISO 14971:2019	Medical devices — Application of risk management to medical devices
6.	ISO TR 24971:2020	Medical devices — Guidance on the application of ISO 14971
7.	EN ISO 10933-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018)
8.	EN 62366-1:2015	Medical devices - Application of usability engineering to medical devices
9.	MEDDEV 2.7.1 Rev.4	Clinical evaluation: Guidance under the Directive 93/42 / EEC and 90/385 / EEC manufacturers and notified bodies
10.	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
11.	EN ISO 10993-10:2013	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
12.	EN ISO 14644-1:2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
13.	EN ISO 14644-2:2015	Cleanrooms and associated controlled environments. Part 2:Monitoring to provide evidence of cleanroom
14.	ISO 14698-1:2003	Cleanrooms and associated controlled environments - Biocontamination control - Part 1: General principles and methods (ISO 14698-1:2003)
15.	ISO 14698-2:2003	Cleanrooms and associated controlled environments - Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data (ISO 14698-2:2003)

Yangzhou,Jiangsu
2025-12-31

DIRECTOR

Ort, Datum / Place, date /
Lieu, date / Luogo, data

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

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