

Manufacturer's Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Manufacturer: MEDCAPTAIN LIFE SCIENCE CO., LTD.
Address: Room 1401, Building 2, Jiayu Science and Technology Park, No. 69 Jin'an Road, Hewan Community, Matian Street, Guangming, 518106 Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA
Single registration number: CN-MF-000006656

EU Authorized Representative: Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestrasse 80, 20537 Hamburg, Germany
 Tel: +49-40-2513175
 Fax: +49-40-255726
 Email: shholding@hotmail.com
Single registration number: DE-AR-000000001

Object of the declaration:

Product name	Classification / rule
Disposable Laryngoscope Blade	Class Is, Rule 5

Conformity assessment: Annex IX Chapters I & III.

As delivered, we, **THE MANUFACTURER**, are exclusively responsible for the Declaration of Conformity and declare that the object of the declaration described above is in conformity with the requirements of the following documents:

Document number	Title	Edition/Date of issue
Regulation (EU) 2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC	On 5 th May, 2017
All harmonized standards which are applicable to the object, as published in the Official Journal of the European Communities.		

Additional information:

Notified body: TÜV SÜD Product service GmbH
Address: Ridlerstraße 65, 80339 Munich, Germany
NB number: 0123
CE marking with NB Number: 

Certificate	Initially issued	Last renewal	Valid until
EU Quality Management System Certificate (No. G11 102877 0012 Rev.01)	2024-02-20	2026-04-21	2027-06-08
EN ISO 13485 QMS Certificate (No. Q5 102877 0007 Rev.06)	2022-06-27	2026-04-21	2028-06-11

Place and date of declaration:

Shenzhen, China; 2026-04-28.

Signed for and behalf of:

MEDCAPTAIN LIFE SCIENCE CO., LTD.

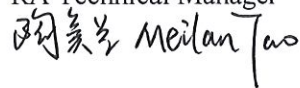
Name:

Meilan Tao

Function (Company):

RA Technical Manager

Signature:

 Meilan Tao 2026-04-28

Annex 1: Product list

No.	Basic UDI-DI (GMN)	EMDN Code	Model	Description
1	697299186VS3201VB	R9002	M1	1#laryngoscope blade
2	697299186VS3201VB	R9002	M2	2#laryngoscope blade
3	697299186VS3201VB	R9002	M3	3#laryngoscope blade
4	697299186VS3201VB	R9002	M4	4#laryngoscope blade
5	697299186VS3201VB	R9002	M3D	3#dedicated laryngoscope blade for adults with difficult airway