EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Name and address of the manufacturer:	Dongguan ZSR Biomedical Technology Company Limited Unit 448, Qingfeng Road, Taihu Village, Sanzhong Village Committee, Qingxi Town, 523651 Dongguan City, Guangdong Province, PEOPLE'S REPUBLIC OF CHINA
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Email:	sales@zsrbiomedical.com
SRN:	CN-MF-000016828
Trademark:	ZSR®
Name and address European Representative:	Caretechion GmbH Niederrheinstraße.71,Düsseldorf,40474,Germany.
SRN:	DE-AR-000005946

As the manufacturer of the following medical device, we herewith declare under our sole responsibility that the stated medical device: /

Product Name:	Disposable Circumcision Anastomat
Product Model& Specification size:	ZSR-DCA-12, ZSR-DCA-14, ZSR-DCA-16, ZSR-DCA-18, ZSR-DCA-22, ZSR-DCA-26, ZSR-DCA-30A, ZSR-DCA-34. ZSR-DCA-12C, ZSR-DCA-14C, ZSR-DCA-16C, ZSR-DCA-18C, ZSR-DCA-22C, ZSR-DCA-26C, ZSR-DCA-28C, ZSR-DCA-30C, ZSR-DCA-34C, ZSR-DCA-36C
Basic UDI-DI:	69363451ZSRDCA001WX
EMDN Code:	H0202020201
Applied Standard:	See attachment 1
Classification acc. to MDR Annex. VIII:	Class IIa, rule 7
Conformity assessment procedure:	Annex IX of Regulation EU 2017/745(MDR)
CE certificate no.:	G10 094301
Issue date:	2025-02-27
Valid until:	2030-02-26
Date CE mark was affixed：	/
Name, address and ID of the Notified Body:	TÜV SÜD Product service GmbH Ridlerstr 65, D-80339 München, Germany CE 0123

is in conformity with Regulation (EU) 2017/745 and with any other relevant Union legislation that provides for the issuing of this EU Declaration of Conformity.All supporting documentations are retained under the premises of the manufacturer.

Quality Manager :Wen Xiuyun

Wen Xiuyun 2025.03.18

Dongguan city of Guangdong,2025.03.18

Place, date

Name and function

Attachemnt 1::Applied Standard List

No.	Standard No.	Standard Name
1.	EN ISO13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes(ISO 13485:2016)
2.	EN ISO14971:2019/A11:2021	Medical devices - Application of risk management to medical devices(ISO 14971:2019)
3.	CEN ISO/TR 24971:2020	Medical devices - Guidance on the application of ISO 14971 (ISO/TR 24971:2020)
4.	EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)
5.	EN ISO 10993-3:2014	Biological evaluation of medical devicesPart 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014）
6.	EN ISO10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity(ISO 10993-5:2009)
7.	EN ISO10993-6:2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:2016)
8.	EN ISO 10993-7:2008/A1:2022	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals - Amendment 1: Applicability of allowable limits for neonates and infants (ISO 10993-7:2008/Amd 1:2019)
9.	EN ISO10993-10:2023	Biological Evaluation Of Medical Devices - Part 10: Tests for skin sensitization (ISO 10993-10:2021)
10.	EN ISO10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)
11.	EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)
12.	EN ISO10993-23:2021	Biological Evaluation Of Medical Devices - Part 23: Tests for irritation (ISO 10993-23:2021)
13.	EN ISO 11135-2014/A1-2019	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
14.	EN ISO 11737-1:2018/A1:2021	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products - Amendment 1 (ISO 11737-1:2018/Amd 1:2021)
15.	EN ISO 11737-2:2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)
16.	EN ISO 11138-1:2017	Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2017)
17.	EN ISO 11138-2:2017	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2017)
18.	EN ISO 14644-1:2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015)
19.	EN ISO 14644-2:2015	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration (ISO 14644-2:2015)
20.	EN ISO 11607-1:2020/A1:2023	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems - Amendment 1: Application of risk management (ISO 11607-1:2019/Amd 1:2023)
21.	EN ISO 11607-2:2020/A1:2023	Packaging for terminally sterilized medical devices - Part

No.	Standard No.	Standard Name
		2: Validation requirements for forming, sealing and assembly processes - Amendment 1: Application of risk management (ISO 11607-2:2019/Amd 1:2023)
22.	ASTM F1980 -21	Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices
23.	EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021)
24.	EN ISO 15223-1:2021/prA1	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements - Amendment 1: Addition of defined term for authorized representative and Modified EC REP symbol to not be country or region specific （ISO 15223-1:2021/Amd 1:2025)
25.	ASTM D4169-23	Standard Practice for Performance Testing of Shipping Containers and Systems
26.	EN 62366-1:2015/A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices
27.	EN ISO 7153-1:2016	Surgical instruments - Materials - Part 1: Metals (ISO 7153-1:2016)
28.	EN 10088-1:2023	Stainless steels - Part 1: List of stainless steels
29.	ASTM F899-23	Standard Specification for Wrought Stainless Steels for Surgical Instruments
30.	MDR (EU) 2017/745	Medical Device Regulation
31.	MEDDEV 2.7/1 rev.4	Clinical evaluation: Guide for manufacturers and notified bodies
32.	MEDDEV 2.12/1 rev.8	Guidance document - Market surveillance - Guidelines on a Medical Devices Vigilance System
33.	MEDDEV 2.12/2 rev.2	Guidance document Medical devices - Market surveillance - Post Market Clinical Follow-up studies
34.	MDCG 2020-8	Post-market clinical follow-up (PMCF) Evaluation Report Template
35.	MDCG 2020-13	Clinical evaluation assessment report template
36.	Regulation (EC) No. 1907/2006	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
37.	Directive (EU) 2011/65	Restriction of Hazardous Substances Directive