



Certificate of Conformity

Product code	Lot No	Sterilization Date	EXP Date
AN*1838R1	200825	20200824	2025-07
AN*1838S1	200825	20200826	2025-07
AN*1925R1	200825	20200825	2025-07
AN*1938R1	200825	20200826	2025-07
AN*1938S1	200825	20200825	2025-07
AN*2025R1	200825	20200824	2025-07
AN*2038R1	200825	20200825	2025-07
AN*2116R1	200825	20200826	2025-07
AN*2125R1	200825	20200826	2025-07
AN*2138R1	200825	20200821	2025-07
AN*2150R1	200825	20200820	2025-07
AN*2232R1	200825	20200820	2025-07
AN*2238R1	200825	20200824	2025-07
AN*2316R1	200825	20200827	2025-07
AN*2325R1	200825	20200822	2025-07
AN*2332R1	200825	20200826	2025-07
AN*2425R1	200825	20200826	2025-07
AN*2516R1	200825	20200824	2025-07
AN*2525R1	200825	20200821	2025-07
AN*2613R1	200825	20200820	2025-07
AN*2623R1	200825	20200821	2025-07
AN*2719R1	200825	20200826	2025-07
AN*3013R1	200825	20200821	2025-07



浙江康德莱医疗器械股份有限公司
ZHEJIANG KINDLY MEDICAL DEVICES CO., LTD.

检验结果/ INSPECTION RESULT:

- 一、生物要求 / Biological Request: 无菌/ asepsis: 合格/Eligible ☒ 不合格/Unqualified ☐ 不检测/No ☐
热原/ PYROGEN: 合格/Eligible ☒ 不合格/Unqualified ☐ 不检测/No ☐
二、化学要求/Chemistry Request: 合格/Eligible ☒ 不合格/Unqualified ☐ 不检测/No ☐
三、物理要求/Physics Request: 合格/Eligible ☒ 不合格/Unqualified ☐ 不检测/No ☐
四、包装要求/Package Request: 合格/Eligible ☒ 不合格/Unqualified ☐ 不检测/No ☐

结论/ CONCLUSION:

灭菌方法: 环氧乙烷/ Sterilization Method: Ethylene Oxide

灭菌地址: 中国浙江省温州市龙湾滨海工业园区滨海五道四路 758 号

Sterilization site: No. 758, 5th Binhai Road, Binhai Industrial Park, Longwan District 325025 Wenzhou, Zhejiang, China.

此产品是根据 EN/ISO 11135 灭菌的/ The Sterility of the products listed above is checked in accordance with EN/ISO 11135

- ☒ 产品生产过程符合 ISO 13485: 2016 要求
CONFORM TO ISO 13485: 2016 REQUIREMENT
☐ 产品生产过程不符合 ISO 13485: 2016 要求
CONFORM TO ISO 13485: 2016 STANDARD
☒ 符合 SX.05.12(EN/ISO 11135)标准
CONFORM TO SX.05.12(EN/ISO 11135) STANDARD
☐ 不符合 SX.05.12(EN/ISO 11135)标准
NOT CONFORM TO SX.05.12(EN/ISO 11135) STANDARD

盖章/Stamp:



检验: 陈刘香 陈静 林小珍

复核: 胡秀仁

批准: 王剑光

INSPECTOR: Liuxiang Chen, Jing Chen, Xiaozhen Lin

VERIFIER: Xiuren Hu

APPROVER: Jianguang Wang

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