EU Declaration of Conformity

Manufacturer:	Huizhou Foryou Medical Devices Co., Ltd.
Add.:	North Shangxia Rd., Dongjiang Hi-tech Industry Park,516005, HuiZhou, P. R. China.
SRN:	CN-MF-000007344
Authorised Representative:	Shanghai International Holding Corp. GmbH (Europe)
Add.:	Eiffestrasse 80, 20537 Hamburg, Germany
SRN of Authorised Representative:	DE-AR-000000001
Product Name:	Calcium alginate dressing,Calcium alginate ribbon
Trade Name:	Sorbalgon® Classic，Sorbalgon®T Classic
Type/Specification:	See Annex Ⅰ
Basic UDI-DI:	Sheet: 69406101AD0005YT;
EMDN Code:	M040402 ALGINATE DRESSINGS
GMDN Code:	43186
Classification:	Ⅱb, REGULATION (EU) 2017/ 745(MDR) Annex Ⅷ, rule 4
Conformity Assessment:	REGULATION (EU) 2017/745, Annex IX Chapter Ⅰ +Ⅲ
General Applicable Regulations:	REGULATION (EU) 2017/745 (MDR), Regulation (EC) No 1907/2006 of the European Parliament and of the Council Concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
Standards Applied:	EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 14971:2019/A11:2021, CEN ISO/TR 24971:2020, EN ISO 4180:2019, ASTM D4169-23, ASTM D4577-19, EN ISO 11607-1:2020, EN ISO 11607-1:2020/A11:2022, EN ISO 11607-1:2020/A1:2023, EN ISO 11607-2:2020, EN ISO 11607-2:2020/A11:2022, EN ISO 11607-2:2020/A1:2023, EN ISO 14644-1:2015, EN ISO 10993-1:2020, EN ISO 10993-3:2014, EN ISO 10993-5:2009, EN ISO 10993-6:2016, ISO 10993-10:2023, EN ISO 10993-11：2018, EN ISO 10993-12:2021, EN ISO 10993-17:2023, EN ISO 10993-18:2020, EN ISO 10993-18:2020/A1:2023, EN ISO 10993-23:2021, EN ISO 11137-1:2015, EN ISO 11137-1:2015/A2:2019, EN ISO 11137-2:2015, EN ISO 11137-2:2015/A1:2023, EN ISO 11137-3:2017, EN ISO 11737-1:2018, EN ISO 11737-1:2018/A1:2021, EN ISO 11737-2:2020, EN ISO 15223-1:2021, EN ISO 20417:2021, ASTM F 1980:2021, EN ISO 14155:2020, MEDDEV. 2.7/1 Rev.4, MEDDEV. 2.12/2 Rev.2, MDCG 2020-5, MDCG 2020-6, MDCG 2020-7, MDCG 2020-8, MDCG 2020-13, MEDDEV 2.12/1 rev 8, EN 13726:2023, EN ISO 1798:2008, EN 62366-1:2015, EN 62366-1:2015/A1:2020, EN 62366-1:2015/AC:2016-09.
Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstr. 65, D-80339 München, Germany
Identification Number:	CE 0123
(EC)Certificate(s):	G10 065520 0040 Rev.02
Expire Date of the Certificate:	2027-09-04

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Regulations and Standards. All supporting documentations are retained under the premises of the manufacturer.

The manufacturer is exclusively responsible for the declaration of conformity.

Signature: 林金团 2026.7.16

Place and Date of Issue:

Huizhou 2026-07-16

Jintuan Lin

Person Responsible for Regulatory Compliance

Annex I

This appendix declares the products included in the above referenced Declaration of Conformity.

REF #	Product Description	Brand Name
999011	Sorbalgon Classic 5cm×5cm P10	Sorbalgon® Classic
999012	Sorbalgon Classic 10cm×10cm P3	Sorbalgon® Classic
999013	Sorbalgon Classic 10cm×10cm P10	Sorbalgon® Classic
999014	Sorbalgon Classic 10cm×20cm P5	Sorbalgon® Classic
999015	Sorbalgon Classic 10cm×20cm P10	Sorbalgon® Classic
999016	Sorbalgon T Classic 2.5cm×30cm P3	Sorbalgon® T Classic
999017	Sorbalgon T Classic 5cm×30cm P5	Sorbalgon® T Classic