

## DECLARATION OF CONFORMITY

<b>Product Name:</b>	Gastric Mucosal Healing Gel
<b>Brand/Model:</b>	GiFIX+/HG0510,HG1010
<b>Country of Origin:</b>	People's Republic of China
<b>Manufacturer:</b>	Bi-trumed Biotech Co., Ltd.
<b>Manufacturing Site:</b>	Building D, 39 Shuangli Street, Haining Economic and Technological Development Area, Jiaxing, P.R. China
<b>GMDN Code:</b>	47764, Wound hydrogel dressing, non-antimicrobial
<b>Risk-based Classification:</b>	Class II a of MDD 93/42 EEC
<b>Medical Device Registration</b>	NMPA Approved
<b>Number of Any Approval:</b>	Certificate No. 20222140160

*Quality Management System certificate*

### ISO 13485: 2016

**Conformity Assessment Body issuing the certificate:** *Procedo International Certification*

**Certificate Number:** *QMS-13-004-2022/A*

**Issuance date:** *21/07/2023*

**Expiry date:** *22/05/2025*

### STANDARD APPLIED

EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 15223-1:2021, EN 62366-1:2015, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO 10993-11:2018, EN ISO 14644-1: 2016, EN ISO 20417:2021, EN ISO17665-1:2006, EN ISO 14155:2020; ISO 11135-2014.

I am fully responsible with all the information provided in this declaration. This declaration of conformity is valid from 01/12/2023.

Authorized Signatory:

*Grace Gao*

Grace Gao /Site Manager

**Bi-trumed Biotech Co., Ltd.**

Date: 01/12/2023

**Bi-Trumed Biotech Co.,Ltd.**

Building D, 39 Shuangli Street, Haining Economic and Technological  
Development Area, Jiaxing, P.R. China