Skyler Biotech Sdn.Bhd
No. 26, Jalan TPP 1/6, Taman Perindustrian
Puchong, 47160 Puchong,
Selangor Darul Ehsan, Malaysia
Tel: +6-03-8051 1140 Fax: +6-03-8051 1140
Email: info@skylerbiotech.com

# Declaration of Conformity

**DECLARATION OF CONFORMITY**

I, *STEVEN SUNG KWAI SHYANG*, hereby declare that the below mentioned medical device—

(i) complies with all the requirements under the Act;

(ii) has been classified according to the classification rules as specified in First Schedule on Rules of Classification of Medical Device; and

(iii) conforms to requirements specified in APPENDIX 1 of Third Schedule on Essential Principles for Safety and Performance of Medical Devices under Medical Devices Regulations 2012.

## (A) Particulars of medical device

| | |
|---|---|
| Generic name: | ULTRASOUND GEL |
| Specified name: Brand/model: | SKYLER BIOTECH |
| Model: | USG - 001 |
| Manufacturer: | SKYLER BIOTECH SDN BHD |
| Country of origin: | MALAYSIA |
| Manufacturing site: | No. 26, Jalan TPP 1/6, Taman Perindustrian Puchong,<br>47160 Puchong, Selangor Darul Ehsan, Malaysia. |
| Risk-based classification: | CLASS A |
| Classification rule: | RULE 5<br>*(Note: according to First Schedule on Rules of Classification of Medical Device)* |
| GMDN code: | 15321 |

Medical device registration number or any approval code: TBA

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## (B) Quality Management System certificate ("QMS")

Conformity Assessment Body issuing the certificate: KGS Certification Sdn Bhd

Certificate number: 510180

Issuance date: 02 August 2021

Expiry date: 27 September 2024

## (C) List of applied standard

| International Standard No. | Title |
|---|---|
| ISO 13485 | Medical Devices "-QMS- Requirement for Regulatory Purpose (ISO 13485)- Version 2003-07-15 |
| ISO 14971 | Medical Devices- Application of Risk Management to Medical Devices |
| ISO 10993 1 | Part 1. Evaluation and testing |
| ISO 10993- 3 | Biological evaluation of medical devices<br>- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity |
| ISO 10993- 5 | Biological evaluation of medical devices<br>- Part 5: Tests for *in vitro* cytotoxicity |
| ISO 10993- 10 | Biological evaluation of medical devices<br>- Part 10: Tests for irritation and sensitization |
| ISO 10993- 11 | Biological evaluation of medical devices<br>- Part 11: Tests for systemic toxicity |
| ISO 15223 | Symbol to be use with medical devices label, labeling and information |
| | |

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BIOTECH

I am fully responsible with all the information provided in this declaration. This declaration of conformity is valid from 1ST (Day) JULY (Month) 2018 (Year).

I fully understand and acknowledge that it is an offence under Section 76 of the Medical Device Act 2012 [*Act 737*] to make, sign or furnish any declaration, certificate or other document which is untrue, inaccurate or misleading.

Authorised Signatory:

Name/Position

4/7/18

Date