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SGS

ADDENDUM 01 TO THE MASTER SERVICES AGREEMENT WITH NUMBER KR/SEL/2533

This Addendum 01 to the Master Services Agreement with number **KR/SEL/2533** (the "MSA") is made on the last date of signature by both Parties ('the Effective Date'), by and between:

1. **SGS BELGIUM NV**, a corporation organized and existing under the laws of Belgium, and having its principal place of business at **SGS House, Noorderlaan 87 - 2030 Antwerpen** (registered no. BE0404 882 750), hereby duly represented by Geofrey De Visscher, Head of Notified Body No 1639 (hereinafter referred to as: "**SGS**").

and

2. **SAEYANG CO., LTD., the legal manufacturer of the devices covered in the proposed scope** and existing under the laws of **Korea** (registered no **503-81-68677)** and having its registered office at **348, Seongseo-ro, Dalseo-gu, Daegu, 42697**, **Korea,** hereby duly represented by **Chang Hoon Jeon, PRRC.** (hereinafter referred to as: "**Client**").

The parties, sub (1) and (2) above shall collectively be referred to as the "**Parties**", and individually as a "**Party**".

Whereas SGS and Client have signed an MSA for certification services under Regulation (EU) 2017/745 and Client wishes to obtain audit services from SGS for certain medical devices that are covered by a certificate or declaration of conformity issued under Council Directives 90/385/EEC or 93/42/EEC.

1. SCOPE OF SERVICES

1.1. Client can request from SGS audit services (the "**Audit Services**") for its devices that are covered by a certificate or declaration of conformity issued under Council Directives 90/385/EEC or 93/42/EEC before 26 May 2021, (the "**Legacy Devices**") in the framework of the extended transition period under the Regulation (EU) 2017/745 on medical devices under Regulation 2023-607 of European Parliament and of Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

Audit Services are required by the Client to be able to apply the transitional provisions of the Legacy Devices and following the written request of Client, SGS will provide a work proposal to Client for such services.

Audit Services shall be understood as yearly on-site surveillance audit in line with associated proposal that can be completed on purpose by SGS by an unannounced audit or a technical file review inducing that Client shall maintain the Legacy Device Technical file up to date and available on request by SGS. Audit Services are covering devices that are listed in the MDD certificate and will be subject to MDR assessment. Devices that are not covered by the MDR application are excluded from the scope of the present addendum and will not be part of the Confirmation Letter.

1.2. SGS will perform the Audit Services to verify if Client complies with the conditions set in the Regulation 2023-607 of European Parliament and of Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

(a) those devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable;

(b) there are no significant changes in the design and intended purpose;

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(c) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;

(d) no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10(9);

(e) no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.

1.3. If following the Audit Services, SGS can determine the Client complies with the above-mentioned conditions, SGS can deliver a declaration that such conditions have been fulfilled by Client at the time of the Audit Services (the **"Confirmation Letter"** as per SGS template LPMDREG5112).

1.4. SGS explicitly clarifies such Confirmation Letter is no certificate or declaration of conformity but it shall guarantee to the Client that with such Confirmation Letter, the Legacy Device is compliant with the conditions necessary to request further access to the EU market, after the expiration of the certificate or declaration of conformity. SGS however never guarantees EU market access and Client furthermore understands that EU market access of a Legacy Device based upon this Confirmation Letter will never guarantee that this Legacy Device will therefore also have access to a non - EU market.

1.5. The Audit Services will only be provided in the period from the Effective Date until 31/12/2027 for higher risk devices and until 31/12/2028 for medium and lower risk devices.

1.6 SGS has the right to terminate the work proposal effective immediately and withdraw the Confirmation Letter effective immediately if one of the following situations occur:

- application review for MDR is done and there is any issue discovered during application review (coding, classification, scope, confirmation from Manufacturer on QMS compliance and do "Refusal of the application" and inform CA accordingly.

OR

- any critical issues are detected during any of the Audit Services

OR

- the client is refusing any Audit Services

1.7 Client's specific obligations relating to this Addendum

Client must comply with requirements defined in MDR (EU) 2017/745 article 120 and in EU regulation 2023/607 and therefore must inform SGS immediately of any change associated to devices and quality management system.

Client must keep up to date their Legacy Device Technical file in order to be able to provide them to SGS on request in less than 5 working days.

2. TERM

2.1. This Addendum shall be effective as of the Effective Date and shall continue in full force and effect until 31/12/2028, it will not be prolonged implicitly (the "**Term**").

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3. GENERAL PROVISIONS

All provisions of the MSA between Parties are applicable to the Audit Services.

This Addendum may be executed in several counterparts, each of which shall be deemed to be an original, and such counterparts together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the Parties hereto have caused duplicate copies of this Addendum to be executed by their duly authorized officers on the dates and at the places indicated below.

Antwerpen, 21-May-24

SGS BELGIUM NV

DocuSigned by:

Date :

By: 621DA8DEE5E2439...

Geofrey De Visscher

Head of Notified Body NB1639

SGS Belgium NV

Daegu, __/___/2024

SAEYANG CO., LTD.

SAEYANG CO., LTD

Date :

By:

JUNG PIL SHIN / PRESIDENT

Client authorized signatory:

Copy to the SGS Local Delivering Office

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