SevenHills Dental Corp.
5-D, Block S.I.E. Factory
Area Sialkot 51310 Pk.
+92(52)3240581

March 3, 2023

AUTHORISED REPRESENTATIVE

We,
SEVEN HILLS DENTAL CORPORATION
5-D, Block S. I. E Shahab Pura, Sialkot-51310-Pakistan.

Being the manufacturers of Class-I Medical devices as per Directive No. 93/42/EEC and Updated Directive 2007/47/EEC hereby authorize

Mr. Zahid Anwar
EU Representative
Certlink Certification Services
P.zza Cavour 18,
20832 Desio (MB),
Italia.
Tel: 0039-347 070 6457
Email: zahid@cert-link.com

To act as authorized representative for CE Marking declaration in the European Union. In this respect, they are authorized to receive, to file or to withdraw any Documents / notice etc. we hereby also agreed to ratify and confirm all acts done by the said representative on our behalf. This authority shall in force until Revoked by us in writing.

For & on Behalf of,
Seven Hills Dental Corporation

Seven Hills Dental Co.
Omer Riaz
Proprietor

Omer Riaz
(Proprietor)

Dental Instruments Specialized

EUROPEAN AUTHORIZED REPRESENTATIVE AGREEMENT

For Class-I medical devices

This is an agreement made on March 03, 2023 and effective as from today by and between **SEVEN HILLS DENTAL CORPORATION a** company organized and existing under the laws of the state of Pakistan, with office at**: 5-D, Block S. I. E Shahab Pura, Sialkot-51310-Pakistan** (''MANUFACTURER''), and **Certlink Certification Services** organized and existing under the laws of **Italia** with office at: **P.zza Cavour 18, 20832 Desio (MB) Italia.** (''AUTHORIZED REPRESENTATIVE''). In consideration of the mutual promises and conditions herein contained, the parties hereto agree as follows:

1.0. APPOINTMENT

1.1. **SEVEN HILLS DENTAL CORPORATION** hereby appoints **Certlink Certification Services** upon the terms and conditions herein contained to be MANUFACTURER's AUTHORIZED PRESENTATIVE with regards to the Directive 93/42/EEC as updated Directive 2007/47/EC in European Economic Area of those Class-I medical devices. Medical devices may be added or re-added or removed to the class-I Medical devices by written amendment delivered by MANUFACTURER to AUTHORIZED REPRESENTATIVE and agreed in writing by AUTHORIZED REPRESENTATIVE. It is understood and agreed that MANUFACTURER may discontinue manufacture of any of the PRODUCTS without obligation to AUTHORIZED REPRESENTATIVE except a 3 months written notification.

2.0. AUTHORIZED REPRESENTATIVE'S ACTIVITIES AND RESPONSIBILITIES

2.1 AUTHORIZED REPRESENTATIVE gives an operational assistance to the MANUFACTURER for maintaining the Technical Documentation provided by the manufacturer.

2.2. When the Technical documentation requested for CE Marking by the Directive 93/42/EEC as updated Directive 2007/47/EC98/79/EC is completed, AUTHORIZED REPRESENTATIVE hereby agrees and undertakes diligently the notifications to its Competent Authority **CERTLINIK**. Upon completion of notifications, AUTHORIZED REPRESENTATIVE issues a declaration of notification for Medical Devices to the MANUFACTURER allowing Medical Devices to be put on the EEA Market.

2.3. AUTHORIZED REPRESENTATIVE will represent the MANUFACTURER before the European Commission for the consultation in case of application of the Safeguard clause by a member state. AUTHORIZED REPRESENTATIVE will represent the MANUFACTURER before any European Competent Authority to put forward the viewpoint of the MANUFACTURER in advance before that any decision of withdrawal or of restriction of sales of its devices is taken by the concerned Member State. AUTHORIZED REPRESENTATIVE shall notify without delay to the MANUFACTURER of any information relative to these consultations and facilitate the physical participation of MANUFACTURER to these meetings.

2.4 AUTHORIZED REPRESENTATIVE is accountable with MANUFACTURER to the Competent Authorities for incident reporting.

- In case of a serious incident reported directly by user to a Competent Authority without report to MANUFACTURER or its local distributor, the AUTHORIZED REPRESENTATIVE is usually directly contacted by this Competent Authority and considered as responsible for answering to any questions relating to the case. AUTHORIZED REPRESENTATIVE shall notify without delay the MANUFACTURER of any of these requests from the concerned Competent Authority.
- In case of incidents known first by the MANUFACTURER, AUTHORIZED REPRESENTATIVE will be immediately informed and will immediately perform with MANUFACTURER the analysis of the incident. If considered as reportable, AUTHORIZED REPRESENTATIVE will write and send to the concerned Competent Authority the initial report including MANUFACTURER's actions if available such as sample analysis, analysis of historic lot records and potential corrective actions with target date

The following time lines apply in a case of:

- **Serious public health threat:** IMMEDIATELY (without any delay that could not be justified) but not later than 2 calendar days after awareness by the MANUFACTURER of this threat.

- **Death or UNANTICIPATED serious deterioration in state of health**: IMMEDIATELY (without any delay that could not be justified) after the MANUFACTURER established a link between the device and the event but not later than 10 elapsed calendar days following the date of awareness of the event.

- **Others:** IMMEDIATELY (without any delay that could not be justified) after the MANUFACTURER established a link between the device and the event but not later than 30 elapsed calendar days following the date of awareness of the event. If after becoming aware of a potentially reportable INCIDENT there is still uncertainty about whether the event is reportable, the MANUFACTURER must submit a report within the timeframe required for that type of INCIDENT.

As soon as information and incident assessment from MANUFACTURER are available, AUTHORIZED REPRESENTATIVE writes and sends the final incident report. In any case, AUTHORIZED REPRESENTATIVE submits these reports to MANUFACTURER for preliminary approval. AUTHORIZED REPRESENTATIVE will keep these records available for inspection by Competent Authorities.

2.5. AUTHORIZED REPRESENTATIVE keeps at disposal of Competent Authorities for any justified request an updated copy of the part of the medical devices Technical Files which shall be kept in the EU Territory. AUTHORIZED REPRESENTATIVE will ask without delay to MANUFACTURER the additional information requested by Competent Authorities. AUTHORIZED REPRESENTATIVE shall not divulge any confidential information with respect to MANUFACTURER's business, except as may be necessary to carry out its activities under this AGREEMENT. This obligation shall survive any expiration or termination of this AGREEMENT.

2.6. AUTHORIZED REPRESENTATIVE shall work closely with MANUFACTURER and shall transmit without delay any information coming from Competent Authorities. In case of special request by Competent Authorities, particularly in relation with incident reporting, AUTHORIZED REPRESENTATIVE will agree with MANUFACTURER on position statement and answers to give to these Authorities. In case of difference in position between the MANUFACTURER and the AUTHORIZED REPRESENTATIVE, the position of the MANUFACTURER will prevail and will be supplied to the Competent Authorities with a formal endorsement of the MANUFACTURER.

3.0. OBLIGATIONS OF MANUFACTURER

3.1. MANUFACTURER shall not put any medical device on the EEA Market without having received the declaration of notification for these medical devices from the competent authority.

3.2. To the best of its ability, MANUFACTURER is obliged to honor all information requests from AUTHORIZED REPRESENTATIVE necessary to comply with E.E.A. regulations concerning MDD Medical Devices. MANUFACTURER shall transmit within 96 hours to the AUTHORIZED REPRESENTATIVE any part of the Technical File requested by a Competent Authority.

3.3. MANUFACTURER shall inform AUTHORIZED REPRESENTATIVE without delay of any risks of incident(s) and transmit any necessary information to protect patients and users. MANUFACTURER and AUTHORIZED REPRESENTATIVE must be in consensus of position statement for reports and answers to give to Competent Authorities.

3.4. MANUFACTURER shall inform AUTHORIZED REPRESENTATIVE by written notice of any change which should be reported in the Technical File as a proof of compliance with the CE Marking. In case of medical devices are withdrawn from the market, MANUFACTURER shall keep EC Declaration of conformities and Technical Files during a period of five (5) years after the last products have been made..

3.5. MANUFACTURER shall labels the medical devices in compliance with E.E.A. Regulations.

3.6. MANUFACTURER shall keep the track record of medical devices distributed in the EEA Community.

3.7. MANUFACTURER shall take the appropriate measures to ensure:

-backward traceability to MANUFACTURER and AUTHORIZED REPRESENTATIVE (name and address of the AUTHORIZED REPRESENTATIVE printed on Medical Devices packaging) and reasonable product traceability to users to minimize the risks in case of recall.

3.8. MANUFACTURER shall inform AUTHORIZED REPRESENTATIVE by written notice of any performance evaluation with medical devices in Europe.

3.9. The Manufacturer shall keep the written report with data collected during the clinical investigation at the disposal of the Competent Authorities.

4. FEES, PAYMENTS AND TRAVEL EXPENSES

MANUFACTURER shall pay AUTHORIZED REPRESENTATIVE'S fees as indicated in Annex 1 to this agreement at the beginning of each contract year. **The fee in relation with Incident handling will be invoiced separately. In case of severe incident(s) conducting to a risk of PRODUCT withdrawal from the E.E.A. market and requiring international travels, AUTHORIZED REPRESENTATIVE will charge travel expenses to MANUFACTURER, after written agreement.**

5. DURATION OF AGREEMENT, TERMINATION

5.1. This AGREEMENT shall enter in force on March 03, 2023 for a period of One year (1) and will be prolonged each one year for the same period by renewal. This AGREEMENT may be terminated by either party at any date by written notification to the other party three (3) months prior the indicated termination date.

AUTHORIZED REPRESENTATIVE:	MANUFACTURER :
CERTLINK CERTIFICATION SERVICES	**SEVEN HILLS DENTAL CORPORATION**

5.2. The AGREEMENT may be terminated forthwith by either party for good cause. Any event shall be deemed good cause for immediate termination that would make it unacceptable for the affected party to continue upholding the AGREEMENT until it can be terminated in the ordinary course of business, in particular:

- If the other party ceases rendering payment;
- If the other party continues to be in material breach of the AGREEMENT even after being notified of such breach, and/or fails to remedy the consequences of such breach.

5.3. Any and all claims for indemnification upon termination of this AGREEMENT or its expiration because of the ending of the AGREEMENT shall be excluded.

5.4. Upon termination of the AGREEMENT, AUTHORIZED REPRESENTATIVE is obliged to send to MANUFACTURER all information and advertising materials, all other objects that are the property of the MANUFACTURER, including all other materials concerning the PRODUCTS that may be in its possession except documents which should be kept as requested by laws. AUTHORIZED REPRESENTATIVE has no rights of retention to these whatsoever as a consequence of any justified or alleged claims vis-à-vis MANUFACTURER.

6. INDUSTRIAL PROPERTY RIGHTS

AUTHORIZED REPRESENTATIVE may not assert any claims whatsoever to the industrial property rights associated with the PRODUCTS.

7. WAIVER

7.1. All claims, without exception, made by the parties against one another on the basis of this AGREEMENT must be asserted in writing within twelve (12) months of termination of the AGREEMENT and/or any part thereof, or else they will be forfeited.

7.2. The waiver of or the failure to enforce a right of this AGREEMENT shall not be deemed as general waiver of such right thereafter.

8. GENERAL PROVISIONS

8.1. No oral ancillary agreements have been entered into. Any written or oral agreements by the parties or arrangements practiced by them prior to concluding this AGREEMENT shall be superseded. All changes and amendments to this AGREEMENT shall only be valid if in writing. This shall also apply if the parties wish to change the requirement of written form.

8.2 This AGREEMENT is subject to the laws of Italia.

AUTHORIZED REPRESENTATIVE: **CERTLINK CERTIFICATION SERVICES**	MANUFACTURER : **SEVEN HILLS DENTAL CORPORATION**
Place: **P.zza Cavour 18** **20832 Desio (MB) Italia.** **Tel: 0039-347 070 6457** **Web:** www.cert-link.com **E-mail:** zahid@cert-link.com	Place: 5-D, Block S. I. E., Shahab Pura, Sialkot-51310-Pakistan. Tel : +92-322-5900580 E-mail: info@sevenhills.pk Web: www.sevenhills.pk
Date : *March 03, 2023* Name : Mr. Zahid Anwar Title : EU REPRESENTATIVE	Date : *March 03, 2023* Name : Mr. Omer Riaz Title : Proprietor

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Seven Hills Dental Co.
Omer Riaz
Proprietor

AUTHORIZED REPRESENTATIVE: **CERTLINK CERTIFICATION SERVICES**	MANUFACTURER : **SEVEN HILLS DENTAL CORPORATION**