LETTER OF CONSENT

(Regulation (EU) 2023/607)

This letter of consent refers to the certificate holder:

Company name of certificate holder: ***DiaDent Group International***

and the following certificate issued in accordance with the Directives 90/385/EEC and/ or 93/42/EEC

Certificate number(s): DD 60149569 0001 (Expiry Date: 2024-05-26), HD 60149568 0001 (Expiry Date: 2024-05-26)

This letter of consent will become an integral part of the certification agreements concluded between the aforementioned certificate holder of certificates according to Directive 90/385/EEC and/ or 93/42/EEC and TÜV Rheinland LGA Products GmbH (TRLP). It amends the current certification agreements between the contract holder and TRLP in order to ensure continued surveillance activities as per Regulation (EU) 2023/607 as a prerequisite to benefit from the extended transition period for medical devices defined within the said regulation.

TÜV Rheinland LGA Products GmbH (TRLP) was accredited as Notified Body for medical devices according to European Directives 90/385/EEC and 93/42/EEC until these expired on May 25, 2021. TÜV Rheinland LGA Products GmbH (TRLP) is now an accredited Notified Body in accordance with the new Regulation on medical devices (EU) 2017/745, also referred to as MDR.

The extensions of the transitional periods beyond May 26, 2024 as published within Regulation (EU) 2023/607 only apply if the conditions laid down in Article 120(3c) MDR are fulfilled. Certificates that expired prior to the publication date of Regulation (EU) 2023/607, the March 20, 2023, remain valid until the dates set out in Art. 120 (3a) MDR amended by Regulation (EU) 2023/607 only if one of the conditions laid down in the second sub-paragraph of Art. 120 (2), points (a) or (b) MDR as amended by Regulation (EU) 2023/607 is fulfilled as well.

According to Article 120 (3e) of Regulation (EU) 2017/745 (MDR) amended by Regulation (EU) 2023/607 the Notified Body that issued the certificates according to Directive 90/385/EEC and/or Directive 93/42/EEC **shall continue to be responsible for the appropriate surveillance** in respect of all the applicable requirements relating to the devices it has certified.

Based on the reasons mentioned above the certificate holder of certificates issued in accordance with Directive 90/385/EEC and/or Directive 93/42/EEC declares consent to

1. confirm, for devices referred to in Art. 120 (3a) and (3b) of Regulation (EU) 2017/745 amended by Regulation (EU) 2023/607 with the requirements, that:
    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;
    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 the May 26, 2024, the manufacturer will have put in place a quality management system in accordance with Regulation (EU) 2017/745 Article 10 (9);
    e. no later than the of May 26, 2024, the manufacturer or its authorized representative will have 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 MDR article 120 or in respect of a device intended to substitute that device, and, no later than September 26, 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.

2. accept that TRLP
   is allowed to perform surveillance activities, such as audits including unannounced audits and assessments (e.g. technical documentation assessments or product testing, where applicable) in order to verify the continuing compliance with the requirements of the Directives 90/385/EEC and/or 93/42/EEC and compliance with the Regulations (EU) 2017/745 and (EU) 2023/607 to implement post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices issued under Directives 90/385/EEC and/or 93/42/EEC also after the expiration date specified on the certificates, and the implementation of a quality management system in accordance with Regulation 2017/745 Article 10(9) latest after May 25, 2024.
3. agree to continue to comply with requirements of TRLP's Testing and Certification Regulations
4. accept that a device with a certificate issued in accordance with Directive 90/385/EEC and/or Directive 93/42/EEC may only be placed on the market or put into service after May 25, 2024, if the requirements of the aforementioned Directives and Regulations are complied with and provided that there are no significant changes in design and intended purpose.
5. understand and accept that
    a. Certificates issued in accordance with Directive 90/385/EEC and/or Directive 93/42/EEC cannot be extended, renewed, or reissued since May 26, 2021.

b. in case of diverging opinion, the interpretation of a significant change and intended purpose and final decision and necessary related activities will be carried out by TRLP based on the documentation handed in by the certification holder for certification according to directive 90/385/EEC and/or Directive 93/42/EEC

c. competent authorities and third parties will be informed if TRLP learns about significant changes in design and intended purpose of devices for which a certificate was issued in accordance with Directive 90/385/EEC and/ or 93/42/EEC before May 26, 2021

6. accept that certificates issued in accordance with Directives 90/385/EEC and/or 93/42/EEC may be cancelled by TRLP based on findings of product and/or quality assurance system evaluations and/or unannounced audits

7. accept appropriate surveillance measures at certificate holder's subcontractors with regard to certifications based on Directive 90/385/EEC and/or Directive 93/42/EEC

8. accept that TRLP has to comply with all future measures, implementing Regulations and recommendations etc. issued by institutions of the European Union and/or national authorities with impact on certificates issued under Directives 90/385/EEC and/ or 93/42/EEC.

9. agree that should one of the aforementioned provisions be or become void or invalid, either in its entirety or in part, the validity of the remaining provisions shall not be affected.

DiaDent Group International, Republic of Korea	Nov, 29. 2023
Place	Date
JAEHOON YOU	
Name of person authorized to sign (in capital letters)	Legally binding signature

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