DEKRA

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Arnhem, 12 June 2023

Subject: **Extension of validity of DEKRA Certification B.V. Certification Agreement for continuation of MDD 93/42/EEC or AIMD 90/385/EEC surveillance activities, in reference to Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulation (EU) 2017/745 as regards the transitional provision for certain medical devices**

Introduction:
Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulation (EU) 2017/745 and (EU) 2017/746 as regards the transitional provision for certain medical devices and in vitro diagnostic medical devices has been published on 20 March 2023 and came into force on the same day.

This Regulation (EU) 2023/607 has amended Regulation (EU) 2017/745 (from here referred to as MDR 2017/745) to now identify that under certain conditions certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC that were still valid on 26 May 2021 and that have not been withdrawn afterwards shall remain valid after the end of the period indicated on the certificate under certain conditions. Additionally should the manufacturer intend to make use of the extension of the validity of the certificates, involvement of a notified body for continued surveillance is required.

This agreement identifies the devices and certificates for which the required conditions are met and that the manufacturer intends to make use of the options for extension of the validity of the certificates. The agreement also identifies the conditions under which DEKRA Certification B.V. will be the notified body responsible for continued surveillance. In order for DEKRA Certification

B.V. to continue these surveillance activities the Certification Agreement in place with the manufacturer will be extended, as detailed further below.

Agreement:
BioComp Industries B.V. has identified the intention to make use of the options for extension of the validity of the certificates as detailed in the amendment of the MDR 207/745 by Regulation (EU) 2023/607.

Evidence has been provided by BioComp Industries B.V. that they meet the following condition(s) for the certificates issued by DEKRA Certification B.V. in accordance with Directives 90/385/EEC and/or 93/42/EEC to remain valid:

- BioComp Industries B.V. holds certificates issued by DEKRA Certification B.V. in accordance with Directives 90/385/EEC and/or 93/42/EEC that were still valid on 26 May 2021 and that have not been withdrawn afterwards and were not expired on 20 March 2023 and:
    (a) Has already lodged a formal application with a notified body in accordance with MDR 2017/745 Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of the device or in respect of the device intended to substitute that device.
    (b) A written agreement in accordance with MDR 2017/745 Section 4.3, second subparagraph, of Annex VII, is already in place between the notified body to which the formal application has been made and BioComp Industries B.V.

Based on evidence provided by BioComp Industries B.V. it has been determined that the following 90/385/EEC and/or 93/42/EEC DEKRA Certification B.V. certificates of BioComp Industries B.V. for the devices indicated below meet the requirements to remain valid:

Certificate number	**Scope and product categories**	**Annex**	**Class & rule**	**Reference to Declaration of Conformity**
2085156DE01	**HA coated dental implants** **HAVD coated dental implants**	II, section 4	III, rule 8	B12 - BC NL Dos.20.012.101 Rev 13 dated 22-10-2021 signed
2172878CE01	**Implants and related instrument set, including accessories for Dental and Cranio Maxilla Facial (CMF) reconstruction:** <u>CMF:</u> - Extra Oral implants - HAVD coated Extra Oral implants	II	 IIb, rule 8 III, rule 8	B12 - BC NL Dos.20.012.101 Rev 13 dated 22-10-2021 signed

Certificate number	Scope and product categories	Annex	Class & rule	Reference to Declaration of Conformity
	- HA coated extra oral implants - Extra Oral Abutments - Healing Abutments - Extra Oral Instruments - Extra Oral Fixation devices <u>Dental:</u> - Dental implants - HA coated dental implants - HAVD coated dental implants - Dental Abutments - Healing Abutments - Dental Instruments - Dental Fixation devices		III, rule 8 IIa, rule 8 IIb, rule 8 IIa, rule 6 IIa, rule 6 IIb, rule 8 III, rule 8 III, rule 8 IIa, rule 8 IIb, rule 8 IIa, rule 6 IIa, rule 6	
2172878DE01	**HA coated extra oral implants** **HAVD coated extra oral implants**	II, section 4	III, rule 8	B12 - BC NL Dos.20.012.101 Rev 13 dated 22-10-2021 signed

By signing this agreement BioComp Industries B.V. also confirms that the following additional requirements of MDR 2017/745 Article 120 3c, as amended by Regulation (EU) 2023/607, are met, and will continue to be met, for all products listed above which will continue to be placed on the market:

- those devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable;
- there are no significant changes in the design and intended purpose;
- 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;

Additionally BioComp Industries B.V. also commits that no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with MDR 2017/745 Article 10(9).

Following from the above information and commitments from BioComp Industries B.V. DEKRA Certification B.V. agrees to be the notified body responsible for the continued appropriate surveillance in accordance with applicable requirements, and in the respect of the applicable devices identified above, as stipulated in MDR 2017/745 Article 120 3e, as amended by Regulation (EU) 2023/607, DEKRA Certification B.V.. This appropriate surveillance shall include at least:

- Surveillance audits in accordance with Directive 90/385/EEC or Directive 93/42/EEC (as applicable), considering also MDR 2017/745 requirements for post market surveillance,

vigilance, registration of economic operators and of devices as required by MDR 2017/745 Article 120
- Assessment of reportable changes
- Assessment of reportable adverse events (vigilance) for impact on certification status

For the specific devices given above for which the certificate can still be considered valid, the certificate validity date and dates until when the products may be placed on the market or put into service are as follows.

Type of Device	**Date until which certificate can still be considered valid**
Class III Class IIb implantable devices excluding well-established technologies (sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)	31 December 2027
Class IIb devices Class IIb implantable devices which are well-established technologies (sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors) Class IIa devices Class I sterile devices Class I devices with a measuring function	31 December 2028

The table above thus also defines the dates until which DEKRA Certification B.V. is responsible for the appropriate surveillance, unless one of the following situations applies:

- BioComp Industries B.V. provides a Notification of Change to inform DEKRA Certification B.V. that devices will no longer be placed on the market or put into service and the certificate should no longer be considered to be valid
- DEKRA Certification B.V. is not the notified body with which the written agreement has been signed for conformity assessment of the device or substitute device in accordance with MDR 2017/745. In this case the notified body with which the written agreement has been signed for conformity assessment of the device or substitute device must take responsibility for surveillance of the device which has a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC. This should be no later than 26 September 2024 as detailed in MDR 2017/745 Article 120 3e, as amended by Regulation (EU) 2023/607. Thus DEKRA Certification B.V.'s responsibility for surveillance will end on 26 September 2024 in this case, or before if a Notification of Change is

provided to confirm that the surveillance activities are now carried out by another Notified Body.

Finally, by signing this agreement DEKRA Certification B.V. and BioComp Industries B.V. agree that current Certification Agreement CA-14-350 which covers the products under the Directive 90/385/EEC and/or Directive 93/42/EEC certificates listed above will thus continue to remain valid until the dates as stipulated above, in order for DEKRA Certification B.V. to meet the required surveillance responsibilities. This also includes that the manufacturer will continue to meet the following responsibilities as stipulated in that Certification Agreement:

- Allowing DEKRA to carry out appropriate surveillance activities in respect of the applicable requirements
- Reporting of significant changes to DEKRA Certification B.V. for assessment
- Reporting of adverse events (vigilance) to DEKRA Certification B.V. for assessment

Should you agree with the above please confirm this through a signature below.

Thus duly agreed, drafted and signed:

BioComp Industries B.V.		DEKRA Certification B.V.	
Vught	(place)	Arnhem	(place)
12 june 2023	(date)	12 June 2023	(date)
T. Godrie	(signature)		(signature)
Teja Godrie	(name)	B.T.M. Holtus	(name)
Managing Director	(title)	Managing Director	(title)