Agreement about the Extension of certificates according to MDD 93/42/EEC issued by DEKRA Certification GmbH for continuation of MDD 93/42/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

hereinafter "**Extension Agreement**"

Parties:

DEKRA Certification GmbH, having its seat in Stuttgart, Germany, hereinafter to be referred to as "DEKRA"

and

KaVo Dental GmbH, having its seat in Biberach, hereinafter to be referred to as Manufacturer,

Introduction:
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 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by notified bodies in accordance with Directive 93/42/EEC that were still valid on 26 May 2021 and that have not been withdrawn afterwards shall remain valid after the end of the period indicated on the certificate under certain conditions.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 will be the notified body responsible for continued surveillance. In order for DEKRA to continue these surveillance activities the Certification Agreement in place with the manufacturer will be extended, as detailed further below.

Agreement:

Extension Agreement

Manufacturer 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 2017/745 by Regulation (EU) 2023/607.

Evidence has been provided by Manufacturer that they meet the following condition(s) for the certificates issued by DEKRA in accordance with Directive 93/42/EEC to remain valid:

- Manufacturer holds certificates issued by DEKRA in accordance with Directive 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. The certificates, if expired, can be considered to be valid, provided that the following conditions are met by the dates indicated:
    (a) Manufacturer has already lodged a formal application with DEKRA 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) For the conditions to be met for the certificate to remain valid DEKRA to which the formal application has been made and Manufacturer must have signed a written agreement in accordance with MDR 2017/745 Section 4.3, second subparagraph, of Annex VII, by no later than 26 September 2024. Should this agreement not be signed by 26 September 2024 the certificate cannot be considered valid.

Based on evidence provided by Manufacturer it has been determined that the certificates according to MDD 93/42/EEC issued by DEKRA Certification GmbH for the devices indicated in annex 1 meet the requirements to remain valid:

By signing this agreement Manufacturer 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 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;

Following from the above information from Manufacturer DEKRA 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. This appropriate surveillance shall include at least:

- Surveillance audits in accordance with 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. This can also include unannounced audits.
- 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 is responsible for the appropriate surveillance, unless one of the following situations applies:
- Manufacturer provides a Notification of Change to inform DEKRA 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 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 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'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.

Extension Agreement

Finally, by signing this agreement DEKRA and Manufacturer agree that the products covered by the Directive 93/42/EEC certificates listed in annex 1 will thus continue to remain valid until the dates as stipulated above, in order for DEKRA to meet the required surveillance responsibilities.

This Extension Agreement is based on the General Terms and Conditions, the General Certification Conditions and the Specific Certification Conditions (MDR/IVDR) of DEKRA Certification GmbH. The following hierarchy applies: Specific Certification Conditions (1); General Certification Conditions (2); General Terms and Conditions (3). The provisions in this agreement take precedence over the General Terms and Conditions and the General and Specific Certification Conditions.

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

We look forward to our successful cooperation.

DEKRA Certification GmbH
i.V. Markus Kopf

Stuttgart, 24.09.2024

Client

KaVo Dental GmbH	Bismarckring 39, 88400 Biberach
Name of the company submitting the application	Address of the company submitting the application
i.V. Kerstin Henseler	
Title, first name, last name of the client	
Biberach, 24.09.2024	
Place and Date (YYYY-MM-DD)	legally binding signature of the client

KaVo Dental GmbH Bismarckring 39 | 88400 Biberach | Germany

Extension Agreement

Annex 1

The following products are covered by this extension agreement

Device name or Basic UDI-DI under the agreement	MDR device classification as proposed by the manufacturer and verified in the pre-application stage	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD certificate, Reference(s) of the device under MDR application, and the NB certificate
PROPHYflex Pulver orange	Class IIa	N/A	Certificate: 51512-16-00 NB: 0124
PROPHYflex Pulver berry	Class IIa	N/A	Certificate: 51512-16-00 NB: 0124
PROPHYflex Pulver cherry	Class IIa	N/A	Certificate: 51512-16-00 NB: 0124
PROPHYflex Pulver mint	Class IIa	N/A	Certificate: 51512-16-00 NB: 0124
RONDOflex 2013 - Pulver 27 µm, 100 g	Class IIa	N/A	Certificate: 51512-16-00 NB: 0124
RONDOflex 2013 - Pulver 27 µm, 1000 g	Class IIa	N/A	Certificate: 51512-16-00 NB: 0124
RONDOflex 2013 - Pulver 50 µm, 100 g	Class IIa	N/A	Certificate: 51512-16-00 NB: 0124
RONDOflex 2013 - Pulver 50 µm, 1000 g	Class IIa	N/A	Certificate: 51512-16-00 NB: 0124
KaVo PROPHYpearls neutral	Class IIa	N/A	Certificate: 51512-16-00 NB: 0124
KaVo PROPHYpearls mint	Class IIa	N/A	Certificate: 51512-16-00 NB: 0124
KaVo PROPHYpearls peach	Class IIa	N/A	Certificate: 51512-16-00 NB: 0124
KaVo PROPHYpearls orange	Class IIa	N/A	Certificate: 51512-16-00 NB: 0124
KaVo PROPHYpearls black currant	Class IIa	N/A	Certificate: 51512-16-00 NB: 0124
KaVo PROPHYflex Perio Powder (1.009.3732)	Class IIa	N/A	Certificate: 51512-16-00 NB: 0124
KaVo PROPHYflex Perio Powder (1.009.5764)	Class IIa	N/A	Certificate: 51512-16-00 NB: 0124