Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Dendia GmbH
Manufacturer address and contact details	Reichsstrasse 126 6800 – Feldkirch Österreich
Single Registration Number (SRN) (if available)	AT-MF-000040359

Notified body name (if applicable)	mdc medical device certification GmbH
Notified body number (if applicable)	0483
Directive Certificate number(s) to which this confirmation is made (if applicable)	D4000900008
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	26.05.2024
End date of extended validity/transition period	31.12.2028

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

Directive Certificate(s) as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was issued after 25 May 2017, was valid on 26 May 2021 and have not been withdrawn afterwards.
    - Expired/expires *after* 20 March 2023:

      Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

Quality Management System (QMS)

- A QMS in accordance with Article 10(9) MDR is in place.

Device(s) as listed in the attached schedule

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Dendia GmbH
Feldkirch, 23.05.2024

Dellagiacoma Ricardo, CEO
r.dellagiacoma@dendiadental.com

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made**	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity**	**Notified Body name and number that issued the Directive Certificate**	**Notified Body name and number where the MDR application was lodged/contract signed**	**End date of extended validity / transition period**
Rotary instruments for dentistry application – Burs, dental, diamond UMDNS 16-669	D4000900008	26.05.2024	mdc medical device certification GmbH -0483	mdc medical device certification GmbH -0483	31.12.2028
Rotary instruments for dentistry application – Ceramic abrasives & burnishers UMDNS 16-412	D4000900008	26.05.2024	mdc medical device certification GmbH -0483	mdc medical device certification GmbH -0483	31.12.2028
Rotary instruments for dentistry application – Burs, dental, carbide UMDNS 16-668	D4000900008	26.05.2024	mdc medical device certification GmbH -0483	mdc medical device certification GmbH -0483	31.12.2028
Rotary instruments for dentistry application – Burs, dental, steel UMDNS – 16-669	D4000900008	26.05.2024	mdc medical device certification GmbH -0483	mdc medical device certification GmbH -0483	31.12.2028
Rotary instruments for dentistry application – Burs, Ora Surgery UMDNS 11-341	D4000900008	26.05.2024	mdc medical device certification GmbH -0483	mdc medical device certification GmbH -0483	31.12.2028

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)