Regulation 2023/607 EU

Manufacturer's SELF-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

- 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	VDW GmbH
Manufacturer address and contact details	Bayerwaldstr. 15 81737 München Germany
Single Registration Number (SRN)	DE-MF-000015941

Notified body name	TÜV Süd Product Service GmbH
Notified body number	0123
Directive Certificate numbers to which this confirmation is made	G1 015409 0035 Rev. 00 G2S 015409 0027 Rev. 00
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	2024-05-26
End date of extended validity / transition period for Directive Certificates	2028-12-31

We, VDW GmbH, in the role as the manufacturer declare under our sole responsibility:

- for the above listed Directive, the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and
- the devices covered by the existing DoCs listed in the Annex I 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 two applicable conditions:

Directive Certificates

- Directive Certificates covering the devices covered by the existing DoCs listed in Annex I were issued after 25 May 2017, were valid on 26 May 2021 and have not been withdrawn afterwards.
- 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.

Formal applications to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made by us to our notified body for the devices covered by the exiting DoC's and listed under Annex I (including unclassified devices) covered by our current existing and signed written agreement will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

Quality Management System (QMS)

Our existing QMS in place is in accordance with Article 10(9) MDR, see valid ISO Certificate

Q5 015409 0033 Rev 00

Signed for and on behalf of the manufacturer VDW GmbH.

Yours Sincerely,

Munich, 12 April 2024

Petra Altmann-Peichl
Director Quality & Regulatory Compliance

Annex I:

Devices Covered by the exiting DoC:

The followings DoCs will be extended acc. EU 2023/607 and still be valid until 31.12.2028 in compliance to MDD 93/42/EEC with commitment of our Notified Body:

Document Name *(certain SKUs listed within the listed DoCs can be affected by commercial discontinuation)*
DoC_Accessories for root canal treatment_Rev02_MDD
DoC_Non-sterile root canal instruments for repeated use_Rev30_MDD
DoC_Paper points to dry the root canal_Rev12_MDD
DoC_Root Canal Filling Points_Rev34_MDD
DoC_Rotating Root Canal Instruments_Rev32_MDD
DoC_Sterile root canal instruments for repeated use_Rev30_MDD
DoC_Sterile root canal instruments for single use_Rev13_MDD
DoC_Size_Tools_Rev00_MDR