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TÜV SÜD Product Service GmbH· Ridlerstr. 65 · 80339 Munich · Germany

To whom it may concern

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
	PS-MHS-RA/ Julia Hoyer	+49 89 50084-191 Julia.Hoyer@tuvsud.com	+49 89 50084-328	2024-01-25	1 of 1

To whom it may concern

We hereby confirm for medical devices already covered by a certificate according to REGULATION (EU) 2017/745 (MDR) that these devices (same devices or devices being substituted) covered by a certificate according to COUNCIL DIRECTIVE 93/42/EEC (MDD) or COUNCIL DIRECTIVE 90/385/EEC (AIMDD) are subject to the extended certificate validity granted under REGULATION (EU) 2023/607[1], prerequisite the respective provisions of MDR, Art. 120(2) are met, so that these devices may be lawfully placed on the market or put into service according to MDR, Art. 120(3c).

Devices covered by a certificate according to COUNCIL DIRECTIVE 98/79/EC (IVDD) may be lawfully placed on the market or put into service in accordance with Art. 110(3) REGULATION (EU) 2017/746 (IVDR) as amended by REGULATION (EU) 2022/112[2].

Kind regards,

Head of Regulatory Affairs

[1] REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

[2] REGULATION (EU) 2022/112 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 January 2022 amending Regulation (EU) 2017/746 as regards transitional provisions for certain in vitro diagnostic medical devices and the deferred application of conditions for in-house devices