

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 as regards the transitional provisions for certain 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	SPIGGLE & THEIS Medizintechnik GmbH
Manufacturer address and contact details	Burghof 14 51491 Overath Germany Phone: +49 2206 90 810
Single Registration Number (SRN)	DE-MF-000006647

Notified body name (if applicable)	<input type="checkbox"/> See attached schedule
Notified body number (if applicable)	<input type="checkbox"/> See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	<input type="checkbox"/> See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	<input type="checkbox"/> See attached schedule
End date of extended validity/transition period	<input type="checkbox"/> See attached schedule

We, as the manufacturer declare under our sole responsibility:

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.