Declaration of Conformity

We

RZ Medizintechnik GmbH
Unter Haßlen 20
78532 Tuttlingen

declare under our sole responsibility, that the attached scheduled products of the product group

Description	UMDNS_Code	class	Rule
Spoon	13-508	I	6
Elevatorium	11-504	I	6
Elevatorium, other	15-218	I	6
Hook	12-028	I	6
Mallet, other	15-229	I	6
Gouge	11-895	I	6
Clamp	16-771	I	6
Clamp Remover	16-787	I	6
Clamp	10-861	I	6
Artery clamp	10-865	I	6
Bulldog clamp	10-868	I	6
Blade, knife	12-234	I	6
curette	11-084	I	6
Ligature	12-332	I	6
Gouge	10-824	I	6
Blade, knife	12-252	I	6
Needleholder	12-726	I	6
Osteotome	12-844	I	6
Forceps	14-257	I	6
Rasp	13-288	I	6
Scissors	13-480	I	6
Spatula	15-249	I	6
Specula	15-602	I	6
Spreader	13-707	I	6
Syringe	13-929	I	6
Punch, biopsy	13-230	I	6
Wound hook	13-373	I	6
Wound hook, fibre optic	15-635	I	6
Forceps	11-774	I	6
Forceps, biopsy	11-775	I	6
Forceps, tissue	11-797	I	6
Dilator	15-215	I	6

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Class I according to rule 6, of MDD 93/42/EEC annex IX,

Have been manufactured under consideration of European Medical Device Directive 93/42/EEC. The Products are conforming to the Essential Requirements of the Medical Device Directive 93/42/EEC Annex I and may therefore be placed into market, labelled with CE. The conformity assessment of the devices according to MDD 93/42/EEC, Annex VII has been performed under our own responsibility.

This declaration is valid until 26.05.2021, for all articles which remain class 1 under MDR and is valid until 26.05.2024 for all articles which become class 1r under MDR.

15.07.2020 / Tuttlingen
Datum/Ort

(Geschäftsführung)

RZ MEDIZINTECHNIK GmbH
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