

DECLARATION OF CONFORMITY

We, the legal **Occlutech GmbH, Winzerlaer Straße 2, 07745 Jena, Germany** manufacturer hereby declare that the above-mentioned products comply with the European Medical Device Directive 93/42/EEC as amended and its relevant transposition into all national laws of the member states into which we place the device(s)

Occlutech® Delivery Set

Product name	Art. Nr.	Size [F]	Distal Angel
Occlutech® Delivery Set	51DS007	7F	45°
Occlutech® Delivery Set	51DS008	8F	45°
Occlutech® Delivery Set	51DS009	9F	45°
Occlutech® Delivery Set	51DS010	19F	45°
Occlutech® Delivery Set	51DS011	11F	45°
Occlutech® Delivery Set	51DS012	12F	45°
Occlutech® Delivery Set	51DS014	14	45°
Occlutech® Delivery Set	51US006	6F	180°
Occlutech® Delivery Set	51US007	7F	180°
Occlutech® Delivery Set	51US008	8F	180°
Occlutech® Delivery Set	51US009	9F	180°
Occlutech® Delivery Set	51CH012	12F	45° x 45°
Occlutech® Delivery Set	51CH014	14F	45° x 45°
Occlutech® Delivery Set	51ES006	6F	45°
Occlutech® Delivery Set	51ES007	7F	45°
Occlutech® Delivery Set	51ES008	8F	45°
Occlutech® Delivery Set	51ES009	9F	45°
Occlutech® Delivery Set	51ES010	10F	45°
Occlutech® Delivery Set	51ES011	11F	45°

Address of involved notified body to evaluate the conformity:	DEKRA Certification GmbH, Handwerkstraße 15, D-70565 Stuttgart, Germany
Identification number of the notified body:	0124
Certificates and date of the current certificate	51030-23-G3, 2018-10-01
Certificates and date of the respective first certificate	51030-23-G0, 2011-08-29
Conformity assessment procedure:	Directive 93/42/EE, Annex II (4)
Classification according to 93/42/EEC, Annex IX:	Class III
Applied Rule for Classification according to 93/42/EEC, Annex IX:	Rule 7
GMDNS Code:	45419 (cardiac occluder delivery kit)
Product identification allowing for traceability: Each lot of product is released for sale in accordance with records certifying compliance with product specifications.	Article number and LOT number
Applicable harmonized standards:	Product related <i>List of Applicable Standards and Regulations</i> (D06K02A02)
Validity of the Declaration of Conformity:	to 2022-02-14

Jena, 2020-07-29



CEO, Dr. Luis Martin-Parras
Occlutech GmbH