

DECLARATION OF CONFORMITY

optimed Medizinische Instrumente GmbH
Ferdinand-Porsche-Straße 11
76275 Ettlingen

hereby declares in its own responsibility that

INTERVENTIONAL NEEDLES

Order codes:
*Please refer to the annexed article range
of TD1029_1.1.7, Rev. 5*

is a Class IIa medical device
reviewed in accordance with Annex II excluding section (IV)

0124

DEKRA Certification GmbH
Handwerkstrasse 15
D-70565 Stuttgart

conforming to the relevant provisions of the Directive 93/42/EEC.
This Declaration of Conformity is valid until 26.05.2024.
The validity corresponds to the validity of the CE-certificate number 50066-16-08.

Ettlingen, 11.05.2021



Frank Wohkittel
Head of Regulatory Affairs



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Person in charge: Christian Eing
 Last amended by: Ruth Siewe
 Reviewed by: Unterliegt keiner Prüfung
 Approved by: Zlatka Schüßler-Tankova

1.1.7 Complete List of the Various Configurations and Variants

The range of interventional needles offered by optimed consists of the following categories:

- Angiography Needles
 - US-cut
- Initial Puncture Needles (with or without marking)
 - US-cut
- Chiba Needles (with or without marking)
 - US-cut
 - bevel-edged

Extension	Reference	Specification
_AGN	1201-1200	Angiography Needle; Needle, 1-part, US-cut; D: 18 G (1.2 mm), L: 70 mm
_IPN	1403-0151	Initial Puncture Needle; Needle, 1-part, US-cut; D: 17.5 G (1.3 mm), L: 150 mm
_IPN	1403-0200	Initial Puncture Needle; Needle, 2-part, hollow stylet: US-cut, outer cannula: blunt tapered, marking; D: 17.5 G (1.3 mm), L: 200 mm
_CHN	1411-1150	Chiba Needle; Needle, 2-part, full stylet: bevel edged, outer cannula: bevel edged, marking; D: 22 G (0.70 mm), L: 150 mm
_CHN	1411-1220	Chiba Needle; Needle, 2-part, full stylet: bevel edged, outer cannula: bevel edged, marking; D: 22 G (0.70 mm), L: 220 mm
_CHN	1413-1090	Chiba Needle; Needle, 2-part, full stylet: round blunt, outer cannula: US-cut, marking; D: 22 G (0.70 mm), L: 90 mm
_CHN	1413-1150	Chiba Needle; Needle, 2-part, full stylet: round blunt, outer cannula: US-cut, marking; D: 22 G (0.70 mm), L: 150 mm
_CHN	1413-1220	Chiba Needle; Needle, 2-part, full stylet: round blunt, outer cannula: US-cut, marking; D: 22 G (0.70 mm), L: 220 mm
_CHN	1413-3220	Chiba Needle; Needle, 2-part full stylet: round blunt, outer cannula: US-cut; D: 19.5 G (0.95 mm), L: 220 mm

Key:

_AGN	Angiography Needle
_IPN	Initial Puncture Needle
_CHN	Chiba Needle

The following raw material is not being sold as single item but as a part of another product (Drainage Set).

Reference	Specification
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Summary Technical Documentation

TD1029_1.1.7

Revision:5

Approved on: 04.12.2020 21:59

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012209090	Chiba Needle; Needle, 2-part, full stylet: round blunt, outer cannula: US-cut; D: 19.5 G (0.95 mm), L: 90 mm
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