

# DECLARATION OF CONFORMITY

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

hereby declares in its own responsibility that

ACCESSORIES IIA  
DILATOR  
SPLITSHEATH  
PERCUTANEOUS INTRODUCER AND SET  
EPSYLAR PERCUTANEOUS INTRODUCER SHEATH  
2-WAY STOPCOCK / 3-WAY STOPCOCK  
HAEMOSTATIC VALVE

Order codes:  
*Please refer to the annexed article range  
of TD1024\_1.1.7, Rev. 10*

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

 **optimed**

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 Last amended by: Ruth Siewe  
 Reviewed by: Unterliegt keiner Prüfung  
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## 1.1.7 Complete List of the Various Configurations and Variants

The classified Ila accessories range offered by optimed consists of:

- Dilators in sizes (diameter) from 5 to 18 F, length 20 cm
- Splitsheaths in sizes (diameter) from 8 to 16 CH, length 20 cm
- Epsylar - Percutaneous Introducer Sheath with removable haemostatic valve from 4 to 8 F, lengths from 45 – 120 cm

The following table shows the available order codes:

Order code	Description
1224-0445	Epsylar - 4F, 45cm Percutaneous Introducer Sheath with removable haemostatic valve
1224-0465	Epsylar - 4F, 65cm Percutaneous Introducer Sheath with removable haemostatic valve
1224-0512	Epsylar - 5F, 120cm Percutaneous Introducer Sheath with removable haemostatic valve
1224-0545	Epsylar - 5F, 45cm Percutaneous Introducer Sheath with removable haemostatic valve
1224-0590	Epsylar - 5F, 90cm Percutaneous Introducer Sheath with removable haemostatic valve
1224-0645	Epsylar - 6F, 45cm Percutaneous Introducer Sheath with removable haemostatic valve
1224-0665	Epsylar - 6F, 65cm Percutaneous Introducer Sheath with removable haemostatic valve
1224-0690	Epsylar - 6F, 90cm Percutaneous Introducer Sheath with removable haemostatic valve
1224-0745	Epsylar - 7F, 45cm Percutaneous Introducer Sheath with removable haemostatic valve
1224-0765	Epsylar - 7F, 65cm Percutaneous Introducer Sheath with removable haemostatic valve
1224-0790	Epsylar - 7F, 90cm Percutaneous Introducer Sheath with removable haemostatic valve
1224-0845	Epsylar - 8F, 45cm Percutaneous Introducer Sheath with removable haemostatic valve
1224-0865	Epsylar - 8F, 65cm Percutaneous Introducer Sheath with removable haemostatic valve
1230-0200	Dilator 5F for .035i/.038i
1230-0300	Dilator 6F for .035i/.038i
1230-0400	Dilator 7F for .035i/.038i
1230-0500	Dilator 8F for .035i/.038i
1230-0600	Dilator 9F for .035i/.038i
1230-0700	Dilator 10F for .035i/.038i
1230-0800	Dilator 12F for .035i/.038i
1230-0900	Dilator 14F für .035i/.038i
1230-1000	Dilator 16F für .035i/.038i
1230-1100	Dilatator 18F for .035i/.038i



**Summary Technical Documentation**

TD1024\_1.1.7

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1235-0500	Split-sheath Dilator 8F for .035i/.038i Guide-wire
1235-0600	Split-sheath Dilator 9F for .035i/.038i Guide-wire
1235-0700	Split-sheath Dilator 10F for .035i/.038i Guide-wire
1235-0901	Splitsheath 12 CH with dilator, for .038/.038 inch GW
<b>Order code</b>	<b>Description</b>
1235-1101	Splitsheath 14 CH with dilator, for .035/.038 inch GW
1235-1301	Splitsheath 16 CH with dilator, for .035/.038 inch GW

The following raw materials are not being sold as single items but they're part of other products, such as Epsylar.

<b>Order code</b>	<b>Description</b>
111200004	3-Way-Stop-cock, Luer Lock

