

## MICRO-TECH EUROPE

### IMPORTANT INFORMATION: CE REGULATORY ASPECTS FOR “CUSTOM MADE” PRODUCTS

As one of the leading stent manufacturers MICRO-TECH sets the highest standard with finest quality and first-class workmanship. Of course, each single stent meets the high medical standards and requirements of the Directive 93/42/EEC on Medical Devices. All stents within the technical data range listed on the back page of this information are covered by our CE certificate.

Stents which are exceeding this technical data range are not covered by our CE certificate and have to be treated as “custom made” products according to Annex VIII section VIII of the Directive 93/42/EEC on Medical Devices. Such stents can only be produced for one single specific patient and are not allowed to carry the CE sign.

For the production of such stents MICRO-TECH only requires a confirmation from the attending doctor the information as stipulated on the back page of the fax order form titled “custom made” stents.

Therefore please check if the technical data of your required stent is within our CE conforming technical data range listed on the back page. If not, please fill out and sign the confirmation of the attending doctor on the back page of the fax order form.

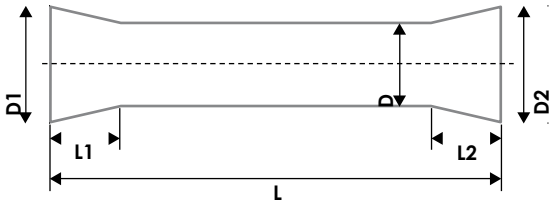
You can find the regulations about “custom made” products as stipulated in the Directive 93/42/EEC on Medical Devices as download at [www.micro-tech-europe.com/en/custom-made-stents](http://www.micro-tech-europe.com/en/custom-made-stents). Comprehensive information about the MDD (Medical Device Directive) is available at [www.dimdi.de](http://www.dimdi.de).

#### **YOUR TRUSTED PARTNER IN ENDOSCOPY**

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EC REP: Shanghai International Holding Corp. GmbH (Europe) | Eiffestraße 80 | 20537 Hamburg | Germany

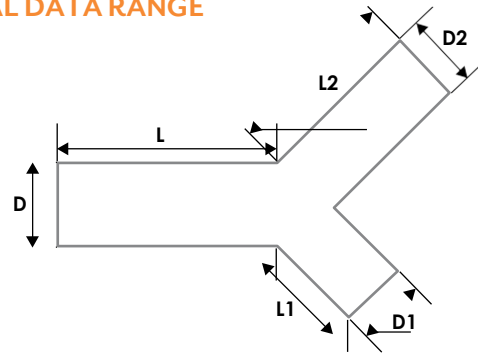
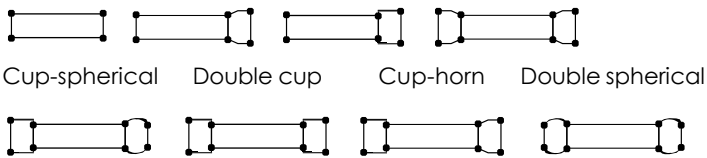
### CE-MICRO-TECH'S CE CONFORMING TECHNICAL DATA RANGE



Oesophageal stent

Design/size in mm	D	L	L1	L2	D1	D2
Straight	14-36	40-200	10-25	5-15	16-70	16-70
Single horn						
Single cup						
Double horn						
Cup spherical			16-70			
Double cup						
Cup-horn						
Double spherical						

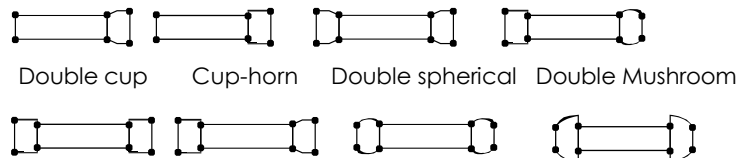
Straight Single horn Single cup Double horn



Intestinal Stent (duodenal-, colonic and rectal stent)

Design/size in mm	D	L	L1	L2	D1	D2
Single horn	18-38	40-160	10-25	5-15	16-70	16-70
Single cup						
Double horn						
Cup spherical						
Double cup				16-70		
Cup-horn						
Double spherical						
Double mushroom						

Single horn Single cup Double horn Cup-spherical



Biliary stent

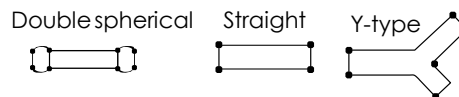
Design/Size in mm	D	L	L1	L2	D1	D2
Straight	6	14-120	-	-	-	-
	8		-	-	-	-
	10		-	-	-	-
horn	6		15	10	8	8
	8		15	10	10	10
	10		15	10	12	12

Straight Single horn Double horn



Tracheal / Bronchial stent

Design/Size in mm	D	L	L1	L2	D1	D2
Double spherical	6-22	20-125	5-15	5-15	12-32	12-32
Straight			-	-	-	-
Y-type			10-40	10-40	10-18	10-18



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