

EC declaration of conformity for medical products

manufacturer: bauer medical GmbH & Co. KG
Bayreuther Str. 9
DE-91301 Forchheim

category: endoscopic accessories

medical product: stone extraction basket

product identity:

ref. number	shape	Ø-basket
BK1-B10-25-23-200	vario	15mm - 25mm
BK1-B10-30-23-200	vario	20mm - 30mm
BK1-B20-20-23-200	hexagonal	20mm
BK1-B20-25-23-200	hexagonal	25mm
BK1-B20-30-23-200	hexagonal	30mm
BK1-B20-35-23-200	hexagonal	35mm
BK1-B21-20-23-200	half twisted	20mm
BK1-B21-25-23-200	half twisted	25mm
BK1-B21-30-23-200	half twisted	30mm
BK1-B21-35-23-200	half twisted	35mm
BK1-B22-20-23-200	fully twisted	20mm
BK1-B22-25-23-200	fully twisted	25mm
BK1-B22-30-23-200	fully twisted	30mm
BK1-B22-35-23-200	fully twisted	35mm

nitinol basket

BK1-C50-25-23-200	hexagonal	25mm
BK1-C50-20-23-200	hexagonal	20mm
BK1-C50-15-23-200	hexagonal	15mm

Guide-Wire Basket

BK1-B80-15-27-200	hexagonal – 4 wires	15mm
BK1-B80-20-27-200	hexagonal – 4 wires	20mm
BK1-B80-25-27-200	hexagonal – 4 wires	25mm
BK1-B81-15-27-200	half-twisted – 4 wires	15mm
BK1-B81-20-27-200	half-twisted – 4 wires	20mm
BK1-B81-25-27-200	half-twisted – 4 wires	25mm
BK1-B82-15-27-200	fully twisted – 4 wires	15mm
BK1-B82-20-27-200	fully twisted – 4 wires	20mm
BK1-B82-25-27-200	fully twisted – 4 wires	25mm
BK1-B90-25-27-200	hexagonal - combi	15mm- 25mm

ref. number	shape	Ø-basket
LT1-B10-25-23-400	vario	15mm - 25mm
LT1-B10-30-23-400	vario	20mm - 30mm
LT1-B20-20-23-400	hexagonal	20mm
LT1-B20-25-23-400	hexagonal	25mm
LT1-B20-30-23-400	hexagonal	30mm
LT1-B20-35-23-400	hexagonal	35mm
LT1-B21-20-23-400	half twisted	20mm
LT1-B21-25-23-400	half twisted	25mm
LT1-B21-30-23-400	half twisted t	30mm
LT1-B21-35-23-400	half twisted	35mm
LT1-B22-20-23-400	fully twisted	20mm
LT1-B22-25-23-400	fully twisted	25mm
LT1-B22-30-23-400	fully twisted	30mm
LT1-B22-35-23-400	fully twisted	35mm

doc stone extraction basket rev.07 date of change: 06.12.2019 changed through: FB

classification: class Is

We hereby declare that the above products correspond to the relevant regulations of Directive 93/ 42 / EEC (2007) concerning medical devices , Annex V and Annex VII, and we take the exclusive responsibility for issuing this declaration.

This declaration of conformity is valid till the 30th of June 2021 or rather till the issuance of a revised declaration of conformity after changing the product.

The following notified body was involved in the declaration of conformity:

ecm GmbH-Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH
Bismarckstr. 106
DE-52066 Aachen
code number 0481

place and date: Forchheim, 06.12.2019

name: Florian Bauer
chief executive

bauer medical GmbH & Co. KG

signature:


