



# EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

## bess pro gmbh

Gustav-Krone-Straße 7  
14167 Berlin  
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

## Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Non-vascular Stents, Head & Neck Surgery Products, Interdisciplinary Products according to annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	532216 MR2
Certificate unique ID	170772759
Effective date	2020-10-26
Expiry date	2024-05-26
Frankfurt am Main	2020-10-26

## DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.



**Annex to certificate**  
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<b>Device family</b>	<b>Device</b>	<b>Class</b>
<b>Non-vascular Stents</b>	Respiratory Stents	IIb
	Esophagus Stents	IIb
	Duodenum Stents	IIb
	Bile Duct and Pancreatic Duct Stents	IIb
	Pseudocyst Stents	IIb
	Colon and Rectum Stents	IIb
<b>Head &amp; Neck Surgery Products</b>	Ventilation Tubes	IIb
	Nasal Splints unrestricted	IIb
	Rhinology Catheters	IIb
	Nasal Splints restricted	IIa
<b>Interdisciplinary Products</b>	Silicone Sheeting unrestricted	IIb
	Silicone Sheeting and Strips restricted	IIa
	Guide Wires	IIa