

# APPENDIX TO EC CERTIFICATE

Appendix to Certificate no.:  
10000463963-PA-NoMA-DNK Rev 0

Valid Until:  
26 May 2024

This is an Appendix issued to EC Certificate issued for manufacturer:

**BK MEDICAL APS**

originally issued in compliance with:

**the Council Directive 93/42/EEC on Medical Devices, as amended**

Based on assessment performed, the following changes to the certification has been accepted as compliance with Council Directive 93/42/EEC on Medical Devices has been established.

Products covered by this Certificate (replaces information on certificate):		
Product Description	Product Name and (REF No)	Class
Vascular transducer	Linear Array Transducer (8809) X18L5s Transducer (9009)	III*
Neurosurgical transducer	Craniotomy Transducer (8862) Burr Hole Transducer (8863) N13C5 Transducer (9062) N11C5s Transducer (9063)	
Ultrasound imaging systems for diagnosis and for monitoring of active therapeutic devices	bkSpecto System (1300) bk3000/bk5000/bkActiv system (2300)	IIb
Transrectal transducers, Transvaginal transducers, and Transducers for monitoring of active therapeutic devices	Endocavity Biplane Transducer (8848) E14CL4b Transducer (9048)	IIb
Transrectal transducers	Anorectal 3D Transducer (2052) Endfire Curved Array Transducer (8667) Prostate Biplane Transducer (8808e) Prostate Triplane Transducer (8818) 3DART Transducer (8838) E11C3b Transducer (9008) E14C4t Transducer (9018) E13C2 Transducer (9029) X14L4 Transducer (9038) 20R3 Transducer (9052)	IIa

Place and date:  
Høvik, 27 March 2023



For the issuing office:  
**DNV Product Assurance AS - Notified Body**  
2460  
Veritasveien 1, 1363 Høvik, Norway



**Hazem Tinawi**  
Technical Reviewer

Intraoperative transducers	4-Way Laparoscopic Transducer (8666-RF) Intraoperative Transducer (8815) T-Shaped Intraoperative Transducer (8816) I14C5I Transducer (9015) I14C5T Transducer (9016) I12C5b Transducer (9024) X12C4 Transducer (9026) I12C5 Transducer (9034) I12C4f Transducer (9066) I13C3f Transducer (9076) Rob12C4 Transducer (9096) Intraoperative Biplane Transducer (8824) ProART Robotic "Drop-in" Transducer (8826)	Ila
Surface transducers	Linear Array Transducer (8670) Linear Array Transducer (8811) Curved Array Transducer (8820e) Curved Array Transducer (8823) Convex Array Transducer (8830) High Frequency Linear Array Transducer (8870) 9C2 Transducer (9002) 13L4w Transducer (9011) 10L2w Transducer (9022) 6C2s Transducer (9023) 8L2 Transducer (9032) 6C2 Transducer (9040) 14L3 Transducer (9051) 18L5 Transducer (9070) 5P1 Transducer (9077) 18L5s Transducer (9081) 5C1e Transducer (9085) 14L3e Transducer (9086) 5P1e Transducer (9087)	Ila
Transvaginal transducers	Endovaginal Transducer (8819) E10C4 Transducer (9019)	Ila
Transesophageal transducers	T7P2m Transducer (9027)	Ila
Biopsy and puncture attachment	Reusable needle guide (UA1282) Reusable needle guide (UA1349) Reusable puncture attachment (UA1256) Reusable biplane biopsy guide (UA1326) Reusable endfire biopsy guide (UA1327) Reusable dual biopsy guide (UA1328)	Ila
Sterile Biopsy and Needle guides	Single-use biopsy guide (UA1257-S14) Extended Single-use biopsy guide (UA1257S17E) Single-use biplane biopsy guide (UA1322-S) Single-use 14G biplane biopsy guide (UA1322-S14) Single-use endfire biopsy guide (UA1323-S) Single-use dual biopsy guide (UA1329-S) Single-use needle guide (UA1336)	Ila

	Single-use needle guide (UA1337) Single-use needle guide (UA1339) Single-use needle guide (UA1345) Single-use needle guide (UA1346)	
Dummy channel brackets	Dummy channel bracket (UA1325) Dummy channel bracket (UA1325-w)	IIa
Sterile Biopsy and Needle guides	Single-use needle guide (UA1338) Single-use needle guide (UA1344)	Is

\* Design assessment is covered by a separate EC-Design Examination Certificate No.: 10000463966-PA-NoMA-DNK Rev 0.0 & 10000463968-PA-NoMA-DNK Rev 0.0.

Appendix History -		
Revision	Description	Issued Date
0.0	Include ref numbers for all devices	28 April 2022
1.0	Correction to product distribution for class III products. Correction of product name. Remove product UA1239.	08 June 2022
2.0	Correction to product list for class IIb as FlexFocus System (1202) has been removed	27 March 2023