

# EC CERTIFICATE

## Full Quality Assurance System

Certificate No.:

10000463963-PA-NoMA-DNK Rev 0.0

Project No.:

PRJN-253180-2021-PA-DNK

Valid Until

26 May 2024

This is to certify that the quality system of:

**BK Medical ApS**

Mileparken 34, 2730 Herlev, Denmark

For design, production and final product inspection/testing of:

**Diagnostic Ultrasound Devices and Sterile Biopsy and Needle guides**

Has been assessed with respect to:

**the conformity assessment procedure described in Annex II of  
Council Directive 93/42/EEC on Medical Devices, as amended**

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:

Høvik, 20 May 2021

For the issuing office:

**Notified Body 2460  
DNV Product Assurance AS**



*Eugenie Winger Husebye*  
**Eugenie Winger Husebye**  
Technical Reviewer

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, [www.dnv.com](http://www.dnv.com)

ICP-4-5-11-MDD-f3, rev.0

## Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

## Certificate history:

Revision	Description	Issue Date
0.0	Transfer of Presafe Denmark A/S (NB 0543) Certificate No. DGM-006 to DNV Product Assurance AS (NB 2460)	20 May 2021

## Products covered by this Certificate:

Product Description	Product Name	Class
Linear Array Transducer	Linear Array Transducer	III*
Craniotomy Transducer	Craniotomy Transducer	
Burr Hole Transducer	Burr Hole Transducer	
X18L5s Transducer	X18L5s Transducer	
N13C5 Transducer	N13C5 Transducer	
N11C5s Transducer	N11C5s Transducer	
Ultrasound imaging systems for diagnosis and for monitoring of active therapeutic devices	FlexFocus System, bkSpectro System, bk3000 System / bk5000 System	IIb
Transrectal transducers, Transvaginal transducers and Transducers for monitoring of active therapeutic devices	Endocavity Biplane Transducer, E14CL4b Transducer	IIb
Transrectal transducers	Anorectal 3D Transducer, Endfire Curved Array Transducer, Prostate Biplane Transducer, Prostate Triplane Transducer, 3DART Transducer, E11C3b Transducer, E14C4t Transducer, E13C2 Transducer, X14L4 Transducer, 20R3 Transducer	IIa
Intraoperative transducers	4-Way Laparoscopic Transducer, Intraoperative Transducer, T-Shaped Intraoperative Transducer, I14C5l Transducer, I14C5T Transducer, I12C5b Transducer, X12C4 Transducer, I12C5 Transducer, I12C4f	IIa

	Transducer, I13C3f Transducer, Rob12C4 Transducer, Intraoperative Biplane Transducer, ProART Robotic "Drop-in" Transducer	
Surface transducers	Linear Array Transducer, Curved Array Transducer, Convex Array Transducer, High Frequency Linear Array, Transducer, 9C2 Transducer, 13L4w Transducer, 10L2w Transducer, 6C2s Transducer, 8L2 Transducer, 6C2 Transducer, 14L3 Transducer, 18L5 Transducer, 5P1 Transducer, 18L5s Transducer, 5C1e Transducer, 14L3e Transducer, 5P1e Transducer	Ila
Transvaginal transducers	Endovaginal Transducer, E10C4 Transducer	Ila
Transesophageal transducers	T7P2m Transducer	Ila
Biopsy and puncture attachment	Reusable needle guide, Reusable puncture attachment, Reusable biplane biopsy guide, Reusable endfire biopsy guide, Reusable dual biopsy guide	Ila
Sterile Biopsy and Needle guides	Single-use biopsy guide, Extended, Single-use biopsy guide, Single-use biplane biopsy guide, Single-use 14G biplane biopsy guide, Single-use endfire biopsy guide, Single-use dual biopsy guide, Single-use needle guide	Ila
Dummy channel brackets	Dummy channel brackets	Ila
Sterile Biopsy and Needle guides	Single-use needle guide	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

### Sites covered by this certificate

Site Name	Address
BK Medical ApS	Mileparken 34, 2730 Herlev, Denmark

## Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. The Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

## Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate