

<b>Legal Manufacturer</b> <b>BK Medical ApS, Mileparken 34, 2730 Herlev, Denmark</b>
Notified Body: DNV Product Assurance AS Notified Body Identification Number: 2460
Compliance Procedure: Annex II except §4 (Class IIa, Class IIb), Annex II including §4 (Class III), Annex II + VII (Class Is)
Certificates: DNV EC Certificate 10000463963-PA-NoMA-DNK DNV EC Design Exam. Certificate 10000463966-PA-NoMA-DNK for Type 8809/9009, DNV EC Design Exam. Certificate 10000463968-PA-NoMA-DNK for Type 8862/8863/9062/9063
Annex IX classes: Class Is (rule 1), Class IIa (rule 5, 6 or 10), Class IIb (rule 9), Class III (rule 6).
<b><u>Class III</u></b> <b>Transducers</b> <ul style="list-style-type: none"><li>• Type 8809, 9009</li><li>• Type 8862, 8863, 9062, 9063</li></ul> <b><u>Class IIb</u></b> <b>Ultrasound systems</b> <ul style="list-style-type: none"><li>• Type 1202</li><li>• Type 1300</li><li>• Type 2300</li></ul> <b>Transducers</b> <ul style="list-style-type: none"><li>• Type 8848, 9048</li></ul> <b><u>Class IIa</u></b> <b>Transducers</b> <ul style="list-style-type: none"><li>• Type 2052</li><li>• Type 8666-RF, 8667, 8670</li><li>• Type 8808e, 8811, 8815, 8816, 8818, 8819, 8820e, 8823, 8824, 8826, 8830, 8838, 8870</li><li>• Type 9002, 9008, 9011, 9015, 9016, 9018, 9019, 9022, 9023, 9024, 9026, 9027, 9029, 9032, 9034, 9038, 9040, 9051, 9052, 9066, 9070, 9076, 9077, 9081, 9085, 9086, 9087, 9096</li></ul> <b>Biopsy &amp; puncture attachments</b> <ul style="list-style-type: none"><li>• UA1256, UA1282, UA1326, UA1327, UA1328, UA1349</li></ul> <b>Sterile Biopsy &amp; needle guides</b> <ul style="list-style-type: none"><li>• UA1257-S14, UA1257S17E, UA1322-S, UA1322-S14, UA1323-S, UA1329-S, UA1336, UA1337, UA1339, UA1345, UA1346</li></ul> <b>Dummy channel brackets</b> <ul style="list-style-type: none"><li>• UA1325, UA1325-w</li></ul> <b><u>Class Is</u></b> <b>Sterile Biopsy &amp; needle guides</b> <ul style="list-style-type: none"><li>• UA1338, UA1344</li></ul>

# EC DECLARATION OF CONFORMITY



"We hereby declare that the above-mentioned products comply with the European Medical Device Directive 93/42/EEC as amended and its relevant transposition into all national laws of the member states into which we place the device(s)"

Herlev, date: 2021.05.26

BK Medical:

A handwritten signature in blue ink, reading "Susanne Faarbæk".

*Susanne Faarbæk – Director Regulatory Affairs*

CER11467 EC Declaration of Conformity