

<p>Legal Manufacturer BK Medical ApS, Mileparken 34, 2730 Herlev, Denmark</p>
<p>Notified Body: DNV Product Assurance AS Notified Body Identification Number: 2460</p>
<p>Compliance Procedure: Annex II except §4 (Class IIa, Class IIb), Annex II including §4 (Class III), Annex II + VII (Class Is)</p>
<p>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</p>
<p>Annex IX classes: Class Is (rule 1), Class IIa (rule 5, 6 or 10), Class IIb (rule 9), Class III (rule 6).</p>
<p><u>Class III</u> Transducers</p> <ul style="list-style-type: none"> • Type 8809, 9009 • Type 8862, 8863, 9062, 9063 <p><u>Class IIb</u> Ultrasound systems</p> <ul style="list-style-type: none"> • Type 1202 • Type 1300 • Type 2300 <p>Transducers</p> <ul style="list-style-type: none"> • Type 8848, 9048 <p><u>Class IIa</u> Transducers</p> <ul style="list-style-type: none"> • Type 2052 • Type 8666-RF, 8667, 8670 • Type 8808e, 8811, 8815, 8816, 8818, 8819, 8820e, 8823, 8824, 8826, 8830, 8838, 8870 • 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 <p>Biopsy & puncture attachments</p> <ul style="list-style-type: none"> • UA1256, UA1282, UA1326, UA1327, UA1328, UA1349 <p>Sterile Biopsy & needle guides</p> <ul style="list-style-type: none"> • UA1257-S14, UA1257S17E, UA1322-S, UA1322-S14, UA1323-S, UA1329-S, UA1336, UA1337, UA1339, UA1345, UA1346 <p>Dummy channel brackets</p> <ul style="list-style-type: none"> • UA1325, UA1325-w <p><u>Class Is</u> Sterile Biopsy & needle guides</p> <ul style="list-style-type: none"> • UA1338, UA1344

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, which appears to read 'Susanne Faarbæk'. The signature is written in a cursive, flowing style.

Susanne Faarbæk – Director Regulatory Affairs

CER11467 EC Declaration of Conformity