

EC DECLARATION OF CONFORMITY

SRA Developments Ltd
Bremridge House, Bremridge,
Ashburton, Devon, TQ13 7JX,
United Kingdom

We hereby declare with sole responsibility that the LOTUS Series 4 Ultrasonic Surgical System and Accessories conforms to the essential requirements of the following:

Medical Device Directive (Council Directive 93/42/EEC of 14 June 1993)

with applied standards:

BS EN ISO13485 / BS EN ISO 17665-1 / BS EN 556-1 / BS EN ISO14971 /
BS EN ISO10993-1 / BS EN 1041 / BS EN ISO 15223-1 / BS EN 11135 / BS EN ISO 11607-1 /
EN60601-1 / EN60601-1-2

CE Marking

Class IIb according to annex II (excluding Section 4) CE 0120

Notified Body

Unit 202B, Worle Parkway,
Weston-super-Mare, Somerset, BS22 6WA
United Kingdom
Nr. 0120

Bremridge, 23.10.2018

Managing Director _____


Martin Heinrich

Schedule of items for the LOTUS Series 4 Ultrasonic Surgical System and Accessories

| Code | Device Name |
|------------|--|
| LG4 | LOTUS Series 4 Generator |
| DS4-200SD | LOTUS Dissecting Shears Straight Handpiece Open 200 |
| DS4-200CD | LOTUS Dissecting Shears Curved Handpiece Open 200 |
| DS4-400CD | LOTUS Dissecting Shears Curved Handpiece Laparoscopic 400 |
| DS4-400CD2 | LOTUS Dissecting Shears Curved Handpiece Laparoscopic 400 (RICHARDSON) |
| DS4-500SD | LOTUS Dissecting Shears Straight Handpiece Bariatric 500 |
| DS4-500CD | LOTUS Dissecting Shears Curved Handpiece Bariatric 500 |
| LR4-200SD | LOTUS Liver Resector Straight Handpiece Open 200 |
| LR4-400SD | LOTUS Liver Resector Straight Handpiece Laparoscopic 400 |
| VW4-200SD | LOTUS Vessel Welder Straight Handpiece Open 200 |
| VW4-400SD | LOTUS Vessel Welder Straight Handpiece Laparoscopic 400 |
| DB3-100D | LOTUS Open Double Blade Sleeve |
| DB3-400D | LOTUS Laparoscopic Double Blade Sleeve |
| ES4-400CT | LOTUS Enhanced Shears Curved Transducer Laparoscopic 400 |
| ES4-400CTE | LOTUS Enhanced Shears Enterotomy Transducer Laparoscopic 400 |
| ES4-200CT | LOTUS Enhanced Shears Curved Transducer Open 200 |
| ES4-500CT | LOTUS Enhanced Shears Curved Transducer Bariatric 500 |
| SV3-200 | LOTUS Dissecting Shears Straight Transducer Open 200 |
| CV3-400 | LOTUS Dissecting Shears Curved Transducer Laparoscopic 400 |
| SV3-500 | LOTUS Dissecting Shears Straight Transducer Bariatric 500 |
| LR3-200 | LOTUS Liver Resector Straight Transducer Open 200 |
| LR3-400 | LOTUS Liver Resector Straight Transducer Laparoscopic 400 |
| W3-200 | LOTUS Vessel Welder Straight Transducer Open 200 |
| W3-400 | LOTUS Vessel Welder Straight Transducer Laparoscopic 400 |
| DB3-100 | LOTUS Double Blade Transducer Open 100 |
| DB3-400 | LOTUS Double Blade Transducer Laparoscopic 400 |
| LF4 | LOTUS LG4 Footswitch |