# DECLARATION OF CONFORMITY

## *Regulation UK MDR 2002*

*The declaration is released under the sole responsibility of the manufacturer*

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|---|---|
| Manufacturer: | **Spencer Italia s.r.l.**<br>Via Provinciale, 12 – 43038 Sala Baganza (PR) – Italy |
| UK Responsible Person: | **Kelyon Ltd**<br>The Maltings, East Tyndall Street Cardiff Bay, Cardiff, CF24 5EA<br>Wales, United Kingdom |
| Medical Device: | 4BELL SILVER+ |
| Code: | ST10500 B |
| Basic UDI–DI: | 805771123SEDIEPORTANT5H |
| SN: | PS25015102 |
| Quantity: | 1 |
| Risk Class :<br>(PART II Regulation 7. Classification of general medical devices, in accordance with Annex IX of Directive 93/42) | I |
| Conformity assessment procedure :<br>(PART II Regulation 17) | NP |
| Rule: | 1 |

**Spencer Italia s.r.l.** declares under is sole responsibility that the above-mentioned medical device is in compliance with the with the relevant essential requirements of Part II in the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) and to the applicable designated standards.

The list of designated standards is reported in the Technical File.

Sala Baganza (PR) - IT, 17-12-25

First name and surname ELENA BERTOLETTI Signature _____

*Person in whose name and on whose behalf this declaration of conformity has been signed.*

Antonio Ciardella (Legal Representative)

Digitally signed by Alexa Gheorghe
Date: 2026.05.28 16:06:07 EEST
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