# *EC Declaration of Conformity*

*according to Directive 93/42/EEC (MDD) issued under the sole responsibility of the manufacturer*

| | |
|---|---|
| **Manufacturer** | STS Medical Group AD<br>Industrial area Sokolovetz<br>2800 Sandanski- Bulgaria |
| **Product** | Product name: Customer packs invasive, sterile or non-sterile, Procedure pack invasive, sterile or non-sterile, Surgical set, sterile or non-sterile, Surgical kit, invasive, sterile or non-sterile<br>Brand name: SECUTRAY<br>REF: CPXXXXX, 11XXX.XX-X, 20XXXXX-X, 66XXXXXX, 1915162, 29XXX, 9604805 9604834, 9514580<br>Description: Suture sets, Suture removal sets, Procedure sets, Set post op, Gynecologic sets, Prokit basic Sonoguard Safety set typ "BG Klinikum Hamburg", Thoracic drainnage procedure kit/set, Revision set, Biopsy set, Bandage set, Single use instrument set, |
| **Classification of Medical device** | Class: IIa Rule: 6 Conformity assessment route: Annex V |
| **CE Marking** | CE 0373 |
| **Notified Body** | Istituto Superiore Di Sanità<br>Viale Regina Elena, 299, 00161-Roma, Italy |
| **EC Certificate** | EC Certificate number: QPZ-1941-20<br>EC Certificate issue date: 06-Aug-2020 |
| **Declaration** | We, the manufacturer,hereby declare that the above-mentioned medical devices:<br>• Comply with the provisions of the Council Directive 93/42/EEC of 14 June 1993 as amended by Directive 2007/47/EC and 120 (3) of Regulation (EU) 2017/745<br>• Are subject to a certified Quality Management System under supervision by a certification body.<br><br>All supporting documentation is retained at the premises of the manufacturer. |

| **Declaration of Conformity** | Revision | Place and Date | Approval by |
|---|---|---|---|
| MDD-DOC-EN-11-03 | 03 | Sandanski,<br>10-Oct-2023 | Anita Chacheva<br>QM Group Manager<br>Signature |