

EC Declaration of Conformity <i>according to Directive 93/42/EEC (MDD) issued under the sole responsibility of the manufacturer</i>			
Manufacturer	STS Medical Group AD Industrial area Sokolovetz 2800 Sandanski- Bulgaria		
Product	Product name: Sterile miscellaneous kits Brand name: SECUTRAY REF: 2XXXX- 4XXXX- 5XXXX- 6XXXX-8XXXX, SEXXXX, 03XXXX, XXXXCE, TPXXXXXXCE, WHHDPXXCE, HCMXXX, 2XXXX-01, 2XXXX-02, 2XXXXYY, 2XXXXY 2XXXXY2Y, 2XXXXY-01, 2XXXXY-03, 2XXXXY-04, 9XXXX, 9XXXX-01, 9XXXX-02, 9XXXXBG, DMXXXX, ZAS3, 9642800		
Classification of Medical device	Class: 1 Rule: 4 Conformity assessment route: Annex V		
CE Marking	CE 0373		
Notified Body	Istituto Superiore Di Sanità Viale Regina Elena, 299, 00161-Roma, Italy		
EC Certificate	EC Certificate number: QPS-0537-20 EC Certificate issue date: 06-Aug-2020		
Declaration	<p>We, the manufacturer, hereby declare that the above-mentioned medical devices:</p> <ul style="list-style-type: none"> • 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 • Are subject to a certified Quality Management System under supervision by a certification body. <p>All supporting documentation is retained at the premises of the manufacturer.</p>		
Declaration of Conformity	Revision	Place and Date	Approval by
MDD-DOC-EN-11-01	03	Sandanski, 10-Oct-2023	Anita Chacheva QM Group Manager
			Signature 