

EC Declaration of Conformity

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

Manufacturer	STS Medical Group AD Industrial area Sokolovetz 2800 Sandanski- Bulgaria		
Product	Product name: Sterile swabs in gauze or non-woven for pharmacy REF: 3XXXX, SALXXXX, NU-XXXXXXXXXXXX, 194XXX, 274XXX, 15400Y, 15400SY, 15400Y-01,15400SY-01. Description: The swabs are folded 18x 40cm and 36x 40cm. Brand name: SECUSORB		
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	We, the manufacturer, hereby declare that the above-mentioned medical devices: <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. All supporting documentation is retained at the premises of the manufacturer.		
Declaration of Conformity	Revision	Place and Date	Approval by
MDD-DOC-EN-05-01	03	Sandanski, 10-Oct-2023	Anita Chacheva QM Group Manager
			Signature
			