EC-Declaration of Conformity
acc. to annex VII, of the Council Directive 93/42/EEC

We

Raguse Gesellschaft für medizinische Produkte mbH
Südfeld 6
59387 Ascheberg-Herbern
Germany

hereby declare under our sole responsibility
as the manufacturer in accordance with the EC Directive 93/42/EEC, Article 1, cl. 2f,
that the specification of the manufactured medical device

DISPOSABLE SURGICAL ACCESSOIRES TO COMPLETE THE COVERAGE PROGRAM

including the described variants

as laid down in the technical file TD-119 is in conformity with the applicable provisions of EC Directive 93/42/EEC.

This EC Declaration of Conformity applies to those products only that have been released acc. to the requirements of the QM-System acc. to Annex VII of the EC Directive 93/42/EEC.

Class of medical device: (acc. to Annex IX of EC Directive 93/42/EEC)	**Is**
Applied harmonized standards:	see technical file, chapter 9
Conformity Assessment Procedure acc. EC Directive 93/42/EEC:	Annex VII in association with Annex V to EC Directive 93/42/EEC
Notified body:	MedCert GmbH, Hamburg CE: 0482

Ascheberg-Herbern, , 23rd March 2018
Place, Date

Joachim Raguse, Geschäftsführer

The declaration of conformity is valid for all shipments after the date of issue.

Anlage zur Konformitätserklärung

RAGUSE REF	MEDLINE REF	DESCRIPTION	PVC-frei	REACH-kompatibel	frei von Stoffen tierischen Ursprungs	PHT-frei	Latex-frei	Klasse	Regel	MD CODE	GMDN CODE	UMDNS CODE	STANDARD	CERTIFICATE NO.	PRODUCT GROUP NO.	DATE OF DECLARATION OF CONFORMITY	DECLARATION OF CONFORMITY VALID UNTIL	DIMDI REG.NO.	INTENDED USE
140004	MSCE4090PPSTA	Absorbent OR table sheet - steril 102 x 229 cm, air permeable	ja	ja	ja	ja	ja	I	1	—	—	—	93/42/EGW Annex V	1324GB4151611 21	119	22.05.2013	22.06.2021	DE/CA22/325b-15	Steriles Einmal-OP-Zubehör zur Ergänzung des Abdeckprogramms. Disposable surgical accessories to complete the coverage program.
140005	ULTRSRB6191STA	Ultrasorbs AP® disposable dry sheet-steril 60 x 91 cm, airpermeable	ja	ja	ja	ja	ja	I	1	—	—	—	93/42/EGW Annex V	1324GB4151611 21	119	22.05.2013	22.06.2021	DE/CA22/325b-15	Steriles Einmal-OP-Zubehör zur Ergänzung des Abdeckprogramms. Disposable surgical accessories to complete the coverage program.
140006	ULTRSB4561ST	Ultrasorbs AP® disposable dry sheet-steril 45 x 61 cm, airpermeable	ja	ja	ja	ja	ja	I	1	—	—	—	93/42/EGW Annex V	1324GB4151611 21	119	22.05.2013	22.06.2021	DE/CA22/325b-15	Steriles Einmal-OP-Zubehör zur Ergänzung des Abdeckprogramms. Disposable surgical accessories to complete the coverage program.

22. NOV. 2016