



DECLARATION OF CONFORMITY

MANUFACTURER: Nuline Limited, Doonview, Patna, Ayrshire, KA6 7JW. UK

PRODUCTS: GDG D - Sterile, single use Dressing, Surgical, Drape and Instrument Packs containing CE marked devices. (Item codes are listed on page 2)

CLASSIFICATION: Sterile System and Procedure Packs – Article 12

CONFORMITY ASSESSMENT ROUTE: MDD Annex V

STATEMENT OF CONFORMITY:

We herewith declare exclusively under sole responsibility that the above-mentioned system and procedure packs meet the provisions of the council directive 93/42/EEC Article 12 for medical devices and have:

- verified the mutual compatibility of the contents in accordance with the manufacturers' instructions
- conducted operations in accordance with these instructions
- packaged the procedure pack
- supplied relevant information to users incorporating relevant instructions from the manufacturers
- the whole activity is subjected to appropriate methods of internal control and inspection.

All supporting documentation is retained under the premises of Nuline Limited, t/a Nuline Medical.

STANDARDS APPLIED: EN13485:2016 Medical devices- Quality management systems- Requirements for regulatory purposes (ISO 13485:2016) DIN EN ISO 13485:2016
ISO 9001:2015 Quality Management Systems Requirements

NOTIFIED BODY: TÜV SÜD Management Services GmbH CE0123
Ridlerstrasse 57, 80339 Munich, Germany

(EC) CERTIFICATE(S): EC Certificate Cert No. G2S 101488 00002 Rev.00
EN13485: 2016 Cert No. Q5 101488 0003 Rev.01
ISO 9001:2016 Cert No. 12 100 58602 TMS

START OF CE-MARKING 18th March 2020

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PLACE OF ISSUE: Patna, UK

DATE OF ISSUE: 23rd March 2023

SIGNATURE: 
~~Tanya Wallace (Mar 23, 2023, 11:49am)~~
TANYA WALLACE
QUALITY ASSURANCE & REGULATORY AFFAIRS MANAGER



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List of Item numbers and descriptions

Item #:	Product name:
ACI358	Spencer Wells Artery Forcep Straight, 20cm Pack
ACI425	McIndoe Scissor Straight 18cm, PAck
ACI120	Hegar Dilator 3-4, Pack
ACI121	Hegar Dilator 5-6, Pack
ACI426	Martin Splinter Forcep 11.5cm, Pack
ACI427	Schroeder Tenaculum Forcep 1:1 Toothed 23cm, Pack
ACI428	Schroeder Tenaculum Forcep 1:1 Toothed Fine 18cm, Pack
ACI430	Sims Curette 4mm/25cm Sharp, Pack
ACI156	Teales Vulsellum Uterine Curved 3:4 Toothed 23cm, Pack
ACP145	IUD Pack



Issuer Nuline medical

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