DECLARATION OF CONFORMITY

1 MANUFACTURER (SRN: UK-MF-000038215)

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Telephone: +44 (0)131 516 3944.

2 EU REPRESENTATIVE (SRN: EL-AR-000037572)

DYSIS Medical SA, Leof Dimokratias 4-6, Neo Psychiko 15451, Greece. Telephone: +30 210 699 7730.

3 PRODUCT

The following products are covered by this Declaration of Conformity:

Device Name	Product Code	Basic UDI-DI
DYSIS Ultra 3.0 Digital Colposcope	DYS404	506047711COLED
DYSIS View Digital Colposcope	VIE001	506047711COLED
DYSIS Disposable Speculum (small)	DSP001	506047711DSPF6
DYSIS Disposable Speculum (medium)	DSP002	506047711DSPF6
DYSIS Disposable Speculum (large)	DSP003	506047711DSPF6
DYSIS Reusable Speculum (small)	RSP001	506047711RSPHC
DYSIS Reusable Speculum (large)	RSP003	506047711RSPHC
DYSIS Reusable Speculum (large wide)	RSP004	506047711RSPHC
DYSIS Reusable Speculum (large wide offset)	RSP005	506047711RSPHC
DYSIS Reusable Speculum (medium narrow)	RSP006	506047711RSPHC
DYSIS Treatment Pipe	TRP001	506047711TRPHK

Classification (Annex VIII of the Medical Device Regulation 2017/745):

Device	Classification	Intended Use
DYSIS Ultra 3.0 Digital Colposcope	Class IIa / Rule 10 as active diagnostic device	DYSIS is a digital colposcope intended to provide magnified viewing of the vagina, cervix and external genitalia. DYSIS is used to diagnose abnormalities and select areas for biopsy. DYSIS acquires, displays and documents high resolution still and sequentially captured images and videos and provides colour coded mapping of the aceto-whitening effect to facilitate and assist assessment and documentation.
DYSIS View Digital Colposcope		
DYSIS Disposable Speculum	Sterile Class I / Rule 5	The disposable, single use speculum is intended to be used to expose the interior of the vagina and allow viewing and accessing a patient's cervix for examination.
DYSIS Reusable Speculum	REUSABLE CLASS I / RULE 5	The reusable stainless steel speculum is intended to be used to expose the interior of the vagina and allow viewing and accessing a patient's cervix for examination.
DYSIS Treatment Pipe	Sterile Class I / Rule 1	The DYSIS treatment pipe is intended for connection to a DYSIS Disposable Speculum during a diathermy procedure to allow the removal of smoke generated during treatment.

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4 NOTIFIED BODY AND CONFORMITY ASSESSMENT ROUTE:

BSI Notified Body 2797. Conformity assessment route: Annex IX CHAPTER I AND III of the Medical Device Regulation 2017/745.

The notified body issues the following certificates to DYSIS Medical:

MDR 760126 R000 - EU Certificate, Full Quality Assurance System
UKCA 772420 - UKCA Certificate, Full Quality Assurance System

5 DECLARATION

We herewith declare that the above-mentioned products conform with the General Safety and Performance Requirements of the Medical Device Regulation 2017/745.

The Technical File and batch records for the manufacture of this device are retained at the premises of DYSIS Medical Ltd.

This EU declaration of conformity is issued under the sole responsibility of DYSIS Medical.

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APPROVED BY:

Stig Pieler
Managing Director (Apgar)

12/8-2025
Approval Date