



EC Declaration of Conformity

Norgine BV, hereby declares that the Medical Devices specified below conform to EC Directive 93/42/EEC as amended, and Norgine BV complies with the Conformity Assessment Route requirements of Annex II excluding section 4. With reference to the Transitional Provisions under MDR (EU) 2017/745, Article 120(3), the Medical Devices specified below may continue to be made available on the market or put into service.

MOVICOL[®], ISOMOL[®], PEGICOL[®]

This Declaration of Conformity is only valid in connection with the batch release documentation for the respective batches of Medical Devices manufactured during the validity of the CE certificate below. These batch records define the batch numbers concerned and covered by this Declaration.

Norgine BV is exclusively responsible for this Declaration of Conformity

Conformity with Annex II (excluding section 4) of the directive is supported by:

CE approval Certificate (Annex II) No.: HD 1676230-1

EN ISO 13485:2016 - Certificate No.: SX 1676230-1

Issued by: "TÜV Rheinland LGA Products GmbH, Tillystraße 2, 90431 Nürnberg"; Notified Body 0197

The undersigned, also declares that no application has been lodged with any other Notified Body for approval of the above Medical Devices.

Signed : *Claudia O'Flynn* Electronically signed by: Claudia O'Flynn
Reason: I have reviewed and approve the content of this document.
Date: Dec 14, 2023 09:44 GMT Date : **14-Dec-2023**

Full Name: Claudia O'Flynn **Position:** Medical Devices Regulatory Manager

Location	Norgine BV, Antonio Vivaldistraat 150, 1083 HP Amsterdam, The Netherlands	Technical Documentation /Product Name:	MOVICOL Family of products
Classification	IIb	Issue	v7.0
Expiry Date:	This EC Declaration of Conformity is valid for the validity period of the CE certificate issued by the Notified Body (the date of signature remains valid until next annual PMS Review).		

Note: A Transitional Declaration of Conformity (dated 22 Sep 2023) is available within section 13.3 of the MOVICOL Technical File. A Note to File summary of evidence to extend validity of the MOVICOL CE certificate to 31 Dec 2028 in line with MDR Article 120(3), as amended, is supported by the following:

- TUV confirmation letter, PLA (signed by both TUV and Norgine) & the Transitional DoC.