OriGENE

Manufacturer: Origene Concepts B.V.
SRN: NL-MF-000010794
Address: Graaf Engelbertlaan 75
4837 DS, Breda
The Netherlands

MDR; Declaration of Conformity, Regulation (EU) 2017/ 745

This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Devices covered and UDI-DIs (GTIN-13):

OriGENE 1 Lower Back	O1	8720648272004
OriGENE 2 Total Spine	O2	8720648272011

Basic UDI-DI (GMN) OriGENE1	GMN 8720648ORIGENE1EC
Basic UDI-DI (GMN) OriGENE2	GMN 8720648ORIGENE2EE
Risk Class	Class I (non-active).
Conformity assessment procedure	Article 52(7) in conjunction with Annex II & III
The devices covered by this declaration are in conformity with Regulation (EU) 2017/745 and applicable General Safety and Performance Requirements (Annex I).	

Intended Purpose OriGENE 1: To prevent, alleviate or cure complaints, pain and/or physical limitations related to the functional movement of the lower (back) portion of the spine
Intended Purpose OriGENE 2: To prevent, alleviate or cure complaints, pain and/or physical limitations related to the functional movement of the total spine, including the neck

Breda, The Netherlands
3 July 2026
Frank M. Bertina, MD
General Manager

Signature: _____
Signed for and on behalf of OriGENE Concepts B.V.

(This DoC shall be valid until 3 July 2031)