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DECLARATION OF CONFORMITY

Expiration 2021-09-15

MANUFACTURER: OASIS® Medical, Inc.
510-528 S. Vermont Ave.
Glendora, CA USA 91741

EUROPEAN REPRESENTATIVE: Donawa Lifescience Consulting Srl
Piazza Albania, 10
00153 Roma, Italy

PRODUCT: Surgical Marking Pen
REF #: 0442 (Fine Tip, Gentian Violet)

CLASSIFICATION: Class Is, Rule 5 according to Annex IX of Directive 93/42/EEC

CONFORMITY ASSESSMENT ROUTE: Annex II of Directive 93/42/EEC

OASIS® MEDICAL, INC. DECLARES THAT THE ABOVE MENTIONED PRODUCTS CONFORM TO THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES. ALL TECHNICAL DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

TO THE BEST OF ITS KNOWLEDGE, INFORMATION AND BELIEF, OASIS® MEDICAL, INC. IS IN COMPLIANCE, IN ALL MATERIAL RESPECTS WITH ITS QUALITY MANAGEMENT SYSTEM ACCORDING TO EN ISO 13485:2016 AND ITS GOOD FAITH UNDERSTANDING OF THE REQUIREMENTS OF THE COUNCIL DIRECTIVE 93/42/EEC. THIS DECLARATION IS ISSUED UNDER THE SOLE RESPONSIBILITY OF OASIS® MEDICAL, INC.

NOTIFIED BODY: DQS 0297 – DQS Medizinprodukte GmbH
August-Schanz-Strasse 21
60433 Frankfurt a.M.
Germany

EC CERTIFICATE(S): EC Certificate Number: 288050 MR2
Issued: 2018-09-16
Valid Until: 2023-09-15

QUALITY MANAGEMENT SYSTEM: EN ISO 13485:2016

CERTIFICATE(S): Certificate Number: 288050 MP2016
Issued: 2018-09-16
Valid Until: 2021-09-15

SIGNATURE:


Wan-Ting Cheh
Regulatory Affairs Specialist, OASIS® Medical, Inc.

02/27/2019
Date