

Declaration of Conformity

for the Davidson Marking System® Tissue Marking Dyes


Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 concerning In Vitro Diagnostic Medical Devices

The undersigned, under their sole responsibility, declares that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Davidson Marking System® Tissue Marking Dyes
Legal Manufacturer: (Name on Label)	Bradley Products Inc 1700 W 94 th St Bloomington, MN 55431 USA
SRN:	Not yet assigned
Basic UDI-DI:	0850043601DMSXF
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	Davidson Marking System® System Tissue Marking Dyes are used laboratories to aid in tissue orientation. They are to be used on excised tissue only. A user in a laboratory manually applies the dye to the margins of an excised tissue sample in order to aid in tissue orientation during later processes.
IVDR Classification:	Class A, non-sterile
Notified Body:	Not Applicable. NB not required for Class A non-sterile
CE Certificate:	Not applicable for Class A.
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234
IVDR Assessment Route:	<i>For Class A, non-sterile: Issuing of the Declaration of Conformity in accordance with Article 17 after drawing up the technical documentation in Annexes II and III of the EU IVDR 2017/746.</i>

Name Sarah OlsonPosition Vice PresidentBloomington, USA

Signed

Date 11/30/2022

Place

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard/CS/Document Name	Description
2017/746	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 concerning In Vitro Diagnostic Medical Devices
EN ISO 13485:2016+A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019+A11:2021	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements
EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer
EN ISO 18113-1:2011	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements

Appendix II – Product Listing/Schedule

Catalogue Number / UDI-DI	Device Description	EMDN Code
2408 00850043601647	Davidson Marking System® 8-Color Set of 2 oz. bottles of marking dye (g, y, bk, r, bl, o, v, l) in a wood tray	W0599
2408-P 00850043601418	Davidson Marking System® 8-Color Set of 2 oz. bottles of marking dye (g, y, bk, r, bl, o, v, l) in a plastic tray	W0599
2407 00850043601425	Davidson Marking System® 7-Color Set of 2 oz. bottles of marking dye (g, y, bk, r, bl, o, v) in a wood tray	W0599
2407-P 00850043601661	Davidson Marking System® 7-Color Set of 2 oz. bottles of marking dye (g, y, bk, r, bl, o, v) in a plastic tray	W0599
2406 00850043601432	Davidson Marking System® 6-Color Set of 2 oz. bottles of marking dye (g, y, bk, r, bl, o) in a wood tray	W0599
2406-P 00850043601678	Davidson Marking System® 6-Color Set of 2 oz. bottles of marking dye (g, y, bk, r, bl, o) in a plastic tray	W0599
2401 00850043601449	Davidson Marking System® 5-Color Set of 2 oz. bottles of marking dye (g, y, bk, r, bl) in a wood tray	W0599
2401-P 00850043601685	Davidson Marking System® 5-Color Set of 2 oz. bottles of marking dye (g, y, bk, r, bl) in a plastic tray	W0599
2403 08500436012403E2	Davidson Marking System® 3-Color Set of 2 oz. bottles of marking dye (choose colors) in a wood tray	W0599
2403-P 08500436012403E2	Davidson Marking System® 3-Color Set of 2 oz. bottles of marking dye (choose colors) in a plastic tray	W0599

1207 00850043601463	Davidson Marking System® 7-Color Set of 1 oz. bottles of marking dye (g, y, bk, r, bl, o, v) in a wood tray	W0599
1207-P 00850043601500	Davidson Marking System® 7-Color Set of 1 oz. bottles of marking dye (g, y, bk, r, bl, o, v) in a plastic tray	W0599
1008-P 00850043601456	Davidson Marking System® 8-Color Set of 3cc bottles of marking dye (3 ea of g, y, bk, r, bl, o, v, l) in a plastic tray	W0599
3408-1 00850043601081	Davidson Marking System® 8 oz green marking dye	W0599
3408-2 00850043601098	Davidson Marking System® 8 oz yellow marking dye	W0599
3408-3 00850043601104	Davidson Marking System® 8 oz black marking dye	W0599
3408-4 00850043601111	Davidson Marking System® 8 oz red marking dye	W0599
3408-5 00850043601128	Davidson Marking System® 8 oz blue marking dye	W0599
3408-6 00850043601227	Davidson Marking System® 8 oz orange marking dye	W0599
3408-7 00850043601135	Davidson Marking System® 8 oz violet marking dye	W0599
3408-8 00850043601234	Davidson Marking System® 8 oz lime marking dye	W0599
1163-1 00850043601241	Davidson Marking System• 2 oz green marking dye	W0599
1163-2 00850043601258	Davidson Marking System• 2 oz yellow marking dye	W0599
1163-3 00850043601265	Davidson Marking System• 2 oz black marking dye	W0599
1163-4 00850043601272	Davidson Marking System• 2 oz red marking dye	W0599
1163-5 00850043601289	Davidson Marking System• 2 oz blue marking dye	W0599
1163-6 00850043601296	Davidson Marking System• 2 oz orange marking dye	W0599
1163-7 00850043601302	Davidson Marking System• 2 oz violet marking dye	W0599
1163-8 00850043601319	Davidson Marking System• 2 oz lime marking dye	W0599
1101-1 00850043601005	Davidson Marking System• 1 oz green marking dye	W0599
1101-2 00850043601012	Davidson Marking System• 1 oz yellow marking dye	W0599
1101-3 00850043601029	Davidson Marking System• 1 oz black marking dye	W0599
1101-4 00850043601036	Davidson Marking System• 1 oz red marking dye	W0599
1101-5 00850043601043	Davidson Marking System• 1 oz blue marking dye	W0599
1101-6 00850043601050	Davidson Marking System• 1 oz orange marking dye	W0599
1101-7 00850043601067	Davidson Marking System• 1 oz violet marking dye	W0599

1101-8 00850043601074	Davidson Marking System• 1 oz lime marking dye	W0599
1013-1 00850043601326	Davidson Marking System• 3cc green marking dye, jar of 40	W0599
1013-2 00850043601333	Davidson Marking System• 3cc yellow marking dye, jar of 40	W0599
1013-3 00850043601340	Davidson Marking System• 3cc black marking dye, jar of 40	W0599
1013-4 00850043601357	Davidson Marking System• 3cc red marking dye, jar of 40	W0599
1013-5 00850043601364	Davidson Marking System• 3cc blue marking dye, jar of 40	W0599
1013-6 00850043601371	Davidson Marking System• 3cc orange marking dye, jar of 40	W0599
1013-7 00850043601388	Davidson Marking System• 3cc violet marking dye, jar of 40	W0599
1013-8 00850043601395	Davidson Marking System• 3cc lime marking dye, jar of 40	W0599
1013-A 00850043601401	Davidson Marking System• 3cc marking dye, assorted colors, jar of 40 (5 ea of g, y, bk, r, bl, o, v, l)	W0599
0003-12345678 00850043601531	Davidson Marking System• 3cc sample pack (1 ea of g, y, bk, r, bl, o, v, l)	W0599

Version History

Version	Compiled by	Date	Description
1.0	S Olson	7/10/22	Original
1.1	S Olson	7/18/22	updated confirming standard, UDI-DI and EMDN. Removed accessories not applicable under this DoC.
1.2	S Olson	8/1/22	Updated conforming standards list and title of documnet
1.3	S Olson	11/30/2022	Updated EMDN code to W0599