

SURGICAL COMPANIES

EU Declaration of Conformity

Revision: 3

FORM

F4-03

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We, **BATRIK Medical Manufacturing Inc., 850 Halpern , Dorval, QC, H9P 1G6, Canada;**

Declare with sole responsibility, that the below-mentioned product(s) have been assessed against Annex VII of the European Council Directive 93/42/EEC, of June 14, 1993, including the 2007/47/EEC amendments, concerning Medical Devices (MDD) and meet the essential requirements of Annex I on this directive. These non-sterile products have been classified as class I as determined by the MDD, Annex IX, Non-invasive devices, rule I.

Intended use: Batrik Color Coding System Padlocks Security Tags are single-use plastic seals used to lock instrument containers and identify general hospital instruments.

This present declaration is also in conformity with the following European standards and Common Specifications: EN ISO 13485:2016, EN 1041:2008 and EN ISO 14971:2012 following European standards and Common Specifications.

The Quality Management System Certification US01/53984 based on the harmonized standard EN ISO 13485:2016 and the EC Certification US19/819943529 support this declaration.

The GMDN code for the Padlock Security Tag is 63406.

This assessment has been conducted by Batrik Medical Manufacturing Inc.

We hereby appoint Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta, to act as European Authorized Representative as stipulated in the Medical Device Directive 93/42/EEC, including the 2007/47/EEC amendments.

Padlock Security Tags**Series 700**

Item No.	Description	UOM
15-701C	White "Clean" Padlock Tags	B-100
15-701-IND	White Padlock with Indicator	B-100
15-701	White Padlock Security Tags	B-100
15-702-IND	Blue Padlock with Indicator	B-100
15-702	Blue Padlock Security Tags	B-100
15-702ST	Blue "Sterile" Padlock Tags	B-100
15-703-IND	Green Padlock with Indicator	B-100
15-703	Green Padlock Security Tags	B-100
15-704-IND	Red Padlock with Indicator	B-100
15-704	Red Padlock Security Tags	B-100
15-704R	Red "Repair" Padlock Tags	B-100
15-705-IND	Yellow Padlock with Indicator	B-100
15-705L	Yellow "Loaner" Padlock Tags	B-100
15-705	Yellow Padlock Security Tags	B-100
15-705S	Yellow "Sharpen" Padlock Tags	B-100
15-706-IND	Pink Padlock with Indicator	B-100
15-706	Pink Padlock Security Tags	B-100
15-707-IND	Orange Padlock with Indicator	B-100
15-707	Orange Padlock Security Tags	B-100
15-709D	Black "Discard" Padlock Tags	B-100
15-709-IND	Black Padlock with Indicator	B-100
15-709	Black Padlock Security Tags	B-100
15-710-IND	White Padlock with Indicator	B-500
15-710	White Padlock Security Tags	B-500
15-711-IND	White Padlock with Indicator	B-200
15-711	White Padlock Security Tags	B-200
15-712-IND	Blue Padlock with Indicator	B-200

Item No.	Description	UOM
15-712	Blue Padlock Security Tags	B-200
15-713-IND	Green Padlock with Indicator	B-200
15-713	Green Padlock Security Tags	B-200
15-714-IND	Red Padlock with Indicator	B-200
15-714	Red Padlock Security Tags	B-200
15-715-IND	Yellow Padlock with Indicator	B-200
15-715	Yellow Padlock Security Tags	B-200
15-716-IND	Pink Padlock with Indicator	B-200
15-716	Pink Padlock Security Tags	B-200
15-717-IND	Orange Padlock with Indicator	B-200
15-717	Orange Padlock Security Tags	B-200
15-719-IND	Black Padlock with Indicator	B-200
15-719	Black Padlock Security Tags	B-200
15-720-IND	Blue Padlock with Indicator	B-500
15-720	Blue Padlock Security Tags	B-500
15-730-IND	Green Padlock with Indicator	B-500
15-730	Green Padlock Security Tags	B-500
15-740-IND	Red Padlock with Indicator	B-500
15-740	Red Padlock Security Tags	B-500
15-750-IND	Yellow Padlock with Indicator	B-500
15-750	Yellow Padlock Security Tags	B-500
15-760-IND	Pink Padlock with Indicator	B-500
15-760	Pink Padlock Security Tags	B-500
15-770-IND	Orange Padlock with Indicator	B-500
15-770	Orange Padlock Security Tags	B-500
15-790-IND	Black Padlock with Indicator	B-500
15-790	Black Padlock Security Tags	B-500

Series 800

Item No.	Description	UOM
15-801C	White "Clean" Padlock Tags	B-100
15-801-IND	White Padlock with Indicator	B-100
15-801	White Padlock Security Tags	B-100
15-802-IND	Blue Padlock with Indicator	B-100

Item No.	Description	UOM
15-812	Blue Padlock Security Tags	B-200
15-813-IND	Green Padlock with Indicator	B-200
15-813	Green Padlock Security Tags	B-200
15-814-IND	Red Padlock with Indicator	B-200

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15-802	Blue Padlock Security Tags	B-100
15-802ST	Blue "Sterile" Padlock Tags	B-100
15-803-IND	Green Padlock with Indicator	B-100
15-803	Green Padlock Security Tags	B-100
Item No.	Description	UOM
15-804-IND	Red Padlock Security Tags	B-100
15-804	Red Padlock Security Tags	B-100
15-804R	Red "Repair" Padlock Tags	B-100
15-805-IND	Yellow Padlock with Indicator	B-100
15-805L	Yellow "Loaner" Padlock Tags	B-100
15-805	Yellow Padlock Security Tags	B-100
15-805S	Yellow "Sharpen" Padlock Tags	B-100
15-806-IND	Pink Padlock with Indicator	B-100
15-806	Pink Padlock Security Tags	B-100
15-807-IND	Orange Padlock Security Tags	B-100
15-807	Orange Padlock Security Tags	B-100
15-809D	Black "Discard" Padlock Tags	B-100
15-809-IND	Black Padlock with Indicator	B-100
15-809	Black Padlock Security Tags	B-100
15-810-IND	White Padlock with Indicator	B-500
15-810	White Padlock Security Tags	B-500
15-811-IND	White Padlock with Indicator	B-200
15-811	White Padlock Security Tags	B-200
15-812-IND	Blue Padlock with Indicator	B-200

15-814	Red Padlock Security Tags	B-200
15-815-IND	Yellow Padlock with Indicator	B-200
15-815	Yellow Padlock Security Tags	B-200
15-816-IND	Pink Padlock with Indicator	B-200
Item No.	Description	UOM
15-816	Pink Padlock Security Tags	B-200
15-817-IND	Orange Padlock with Indicator	B-200
15-817	Orange Padlock Security Tags	B-200
15-819-IND	Black Padlock with Indicator	B-200
15-819	Black Padlock Security Tags	B-200
15-820-IND	Blue Padlock with Indicator	B-500
15-820	Blue Padlock Security Tags	B-500
15-830-IND	Green Padlock with Indicator	B-500
15-830	Green Padlock Security Tags	B-500
15-840-IND	Red Padlock with Indicator	B-500
15-840	Red Padlock Security Tags	B-500
15-850-IND	Yellow Padlock with Indicator	B-500
15-850	Yellow Padlock Security Tags	B-500
15-860-IND	Pink Padlock with Indicator	B-500
15-860	Pink Padlock Security Tags	B-500
15-870-IND	Orange Padlock with Indicator	B-500
15-870	Orange Padlock Security Tags	B-500
15-890-IND	Black Padlock with Indicator	B-500
15-890	Black Padlock Security Tags	B-500

Series 900

Item No.	Description	UOM
15-901C	White "Clean" Padlock Tags	B-100
15-901-IND	White Padlock with Indicator	B-100
15-901	White Padlock Security Tags	B-100
15-902-IND	Blue Padlock with Indicator	B-100
15-902	Blue Padlock Security Tags	B-100
15-902ST	Blue "Sterile" Padlock Tags	B-100
15-903-IND	Green Padlock with Indicator	B-100
15-903	Green Padlock Security Tags	B-100
15-904-IND	Red Padlock Security Tags	B-100
15-904	Red Padlock Security Tags	B-100
15-904R	Red "Repair" Padlock Tags	B-100
15-905-IND	Yellow Padlock with Indicator	B-100
15-905L	Yellow "Loaner" Padlock Tags	B-100
15-905	Yellow Padlock Security Tags	B-100
15-905S	Yellow "Sharpen" Padlock Tags	B-100
15-906-IND	Pink Padlock with Indicator	B-100
15-906	Pink Padlock Security Tags	B-100
15-907-IND	Orange Padlock Security Tags	B-100
15-907	Orange Padlock Security Tags	B-100
15-909D	Black "Discard" Padlock Tags	B-100
15-909-IND	Black Padlock with Indicator	B-100
15-909	Black Padlock Security Tags	B-100
15-910-IND	White Padlock with Indicator	B-500
15-910	White Padlock Security Tags	B-500
15-911-IND	White Padlock with Indicator	B-200
15-911	White Padlock Security Tags	B-200
15-912-IND	Blue Padlock with Indicator	B-200

Item No.	Description	UOM
15-912	Blue Padlock Security Tags	B-200
15-913-IND	Green Padlock with Indicator	B-200
15-913	Green Padlock Security Tags	B-200
15-914-IND	Red Padlock with Indicator	B-200
15-914	Red Padlock Security Tags	B-200
15-915-IND	Yellow Padlock with Indicator	B-200
15-915	Yellow Padlock Security Tags	B-200
15-916-IND	Pink Padlock with Indicator	B-200
15-916	Pink Padlock Security Tags	B-200
15-917-IND	Orange Padlock with Indicator	B-200
15-917	Orange Padlock Security Tags	B-200
15-919-IND	Black Padlock with Indicator	B-200
15-919	Black Padlock Security Tags	B-200
15-920-IND	Blue Padlock with Indicator	B-500
15-920	Blue Padlock Security Tags	B-500
15-930-IND	Green Padlock with Indicator	B-500
15-930	Green Padlock Security Tags	B-500
15-940-IND	Red Padlock with Indicator	B-500
15-940	Red Padlock Security Tags	B-500
15-950-IND	Yellow Padlock with Indicator	B-500
15-950	Yellow Padlock Security Tags	B-500
15-960-IND	Pink Padlock with Indicator	B-500
15-960	Pink Padlock Security Tags	B-500
15-970-IND	Orange Padlock with Indicator	B-500
15-970	Orange Padlock Security Tags	B-500
15-990-IND	Black Padlock with Indicator	B-500
15-990	Black Padlock Security Tags	B-500

Manufacturer's signature: Suzy Bairos, Vice-President
Batrik Medical Manufacturing Inc.

Date: December 23, 2019