
	Company Name: SU Instruments		Doc. # MDR/DOC-01/00	Issue 01
	EC Declaration of Conformity: Reusable Surgical and Dental Instruments Class I (See Annex 1 Product List)			
	Date: 31-03-2023	Page 1 of 4 (Prepared / Revised by: QA Manager)		
	Revision History		Revision Detail	
Revision Level: 00 / Latest Revision Date: 31-03-2023				-

EC DECLARATION OF CONFORMITY

SU Instruments, declares under our sole responsibility that our Class 1 reusable Surgical and Dental Instruments listed in Annex 1 (product list) are manufactured in conformity with the requirements of Council Directive 93/42/EEC of June 1993, Annex VII date of issue 14.06.1993 and quality management system certified to ISO 13485:2016. We are presently undergoing transition to MDR 2017/745.

Device Description:	<u>Reusable Surgical and Dental Instruments Class I</u> (See Annex 1 Product List)
MDR Classification	Class: I Class: Ir (Reusable Invasive Devices) Rule: 06 according to annexure VIII of MDR 2017/745 All surgically invasive devices intended for transient use are in Class IIa unless they: <u>are reusable surgical instruments, in which case they are classified as class I</u>
Assessment Route:	Annex IX (Quality Management System and Technical Documentation)
EU Rep:	Name: Yellow's medical instruments GmbH Address: Max-Planck Str. 3, D-12489 Berlin Tel no: +493023458995 Email: sales@yellows-instruments.info
Applicable Standards	ISO 13485:2016, EN ISO 14971:2012, EN ISO 15223-1:2016, EN 1041:2008, ISO 10993-1:2009, ISO 10993-4:2017, ISO 10993-5:2009, ISO 10993-10:2010, ISO 10993-11:2017, MEDDEV 2. 4/1 Rev. 9, ISO 17664:2021, EN 10088-1:2014, ISO 7153-1:2016, ASTM F899:2020, BS 5194-2:1989, ISO 7151:1988
Biocompatibility:	Stainless Steel used is biocompatible and recommended for Medical Application

Approved By:	CEO		Date: 31-03-2023
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SR	Codes	Description	Size
1.	SUBBC0044	Delicate Scissors straight delicate pattern sharp/sharp large rings	115 mm (4 1/2")
2.	SUBBC0055	Delicate Scissors curved delicate pattern sharp/sharp large rings	115 mm (4 1/2")
3.	SUBBC0066	JOSEPH Dissecting Scissors straight delicate pattern sharp/sharp large rings	150 mm (6")
4.	SUBBC0077	JOSEPH Dissecting Scissors curved delicate pattern sharp/sharp large rings	150 mm (6")
5.	SUBBC0088	STEVENS Tenotomy Scissors straight delicate pattern sharp/sharp large rings	115 mm (4 1/2")
6.	SUBBC0099	STEVENS Tenotomy Scissors curved delicate pattern sharp/sharp large rings	115 mm (4 1/2")
7.	SUBBC0100	STEVENS Tenotomy Scissors straight delicate pattern blunt/blunt large rings	115 mm (4 1/2")
8.	SUBBC0111	STEVENS Tenotomy Scissors curved delicate pattern blunt/blunt large rings	115 mm (4 1/2")
9.	SUBBC0155	REYNOLDS-JAMESON Dissecting Scissors curved delicate pattern blunt/blunt large rings	140 mm (5 1/2")
10.	SUBBC0177	Delicate Scissors curved delicate pattern blades outside semi-sharp sharp/sharp large rings	140 mm (5 1/2")
11.	SUBBC0200	Dissecting Scissors straight delicate pattern blunt/blunt large rings	115 mm (4 1/2")
12.	SUBBC0211	Dissecting Scissors curved delicate pattern blunt/blunt large rings	115 mm (4 1/2")
13.	SUBBC0222	METZENBAUM (BABY) Dissecting Scissors straight delicate pattern blunt/blunt large rings	145 mm (5 3/4")
14.	SUBBC0233	METZENBAUM (BABY) Dissecting Scissors curved delicate pattern blunt/blunt large rings	145 mm (5 3/4")
15.	SUBBC0266	RAGNELL Dissecting Scissors straight delicate pattern special flat blunt points large rings	135 mm (5 1/4")
16.	SUBBC0277	RAGNELL Dissecting Scissors curved delicate pattern special flat blunt points large rings	135 mm (5 1/4")
17.	SUBBC0299	RAGNELL Dissecting Scissors curved delicate pattern special flat blunt points large rings	150 mm (6")
18.	SUBBC0300	Vascular Scissors straight delicate	120 mm (4



		pattern 1 blade probe pointed	3/4"
19.	SUBBC0333	Strabismus Scissors angled to side 2 blades probe pointed	115 mm (4 1/2")
20.	SUBBC0344	Vascular Scissors straight probe tip	145 mm (5 3/4")
21.	SUBBC0500	Delicate Scissors straight delicate pattern sharp/sharp	110 mm (4 1/4")
22.	SUBBC0566	Delicate Scissors straight delicate pattern sharp/sharp	95 mm (3 3/4")
23.	SUBBC0577	Delicate Scissors curved delicate pattern sharp/sharp	95 mm (3 3/4")
24.	SUBBC0600	Delicate Scissors straight delicate pattern sharp/sharp	110 mm (4 1/4")
25.	SUBBC0611	Delicate Scissors curved delicate pattern sharp/sharp	110 mm (4 1/4")
26.	SUBBC0644	Delicate Scissors straight delicate pattern sharp/sharp	120 mm (4 3/4")
27.	SUBBC0655	Delicate Scissors curved delicate pattern sharp/sharp	120 mm (4 3/4")
28.	SUBBC1000	Delicate Scissors straight sharp/sharp	90 mm (3 1/2")
29.	SUBBC1011	Delicate Scissors curved sharp/sharp	90 mm (3 1/2")
30.	SUBBC1066	Delicate Scissors straight delicate pattern sharp/sharp	115 mm (4 1/2")
31.	SUBBC1100+A35:C65B35A35:C6A35:C64	Delicate Scissors straight sharp/sharp	110 mm (4 1/4")
32.	SUBBC1100	USUSI Delicate Scissors straight delicate pattern sharp/sharp sterile disposable pack of 20 pcs single packed	110 mm (4 1/4")
33.	SUBBC1111	Delicate Scissors curved sharp/sharp	110 mm (4 1/4")
34.	SUBBC1122	Delicate Scissors straight sharp/blunt	110 mm (4 1/4")
35.	SUBBC1133	Delicate Scissors curved sharp/blunt	110 mm (4 1/4")
36.	SUBBC1177	Delicate Scissors angled to side sharp/sharp	110 mm (4 1/4")
37.	SUBBC1300	Delicate Scissors straight sharp/sharp	120 mm (4 3/4")
38.	SUBBC1311	Delicate Scissors curved sharp/sharp	120 mm (4 3/4")
39.	SUBBC1355	Delicate Scissors curved blunt/blunt	120 mm (4 3/4")
40.	SUBBC1400	Delicate Scissors straight sharp/sharp	130 mm (5 1/8")
41.	SUBBC1411	Delicate Scissors curved sharp/sharp	130 mm (5 1/8")



42.	SUBBC1444	Delicate Scissors straight blunt/blunt	130 mm (5 1/8")
43.	SUBBC1455	Delicate Scissors curved blunt/blunt	130 mm (5 1/8")
44.	SUBBC1533	CHADWICK Delicate Scissors strongly curved delicate pattern sharp/sharp	115 mm (4 1/2")
45.	SUBBC1544	LA GRANGE Delicate Scissors curved s-shaped serrated (one blade) sharp/sharp	115 mm (4 1/2")
46.	SUBBC1566	JOSEPH Dissecting Scissors straight delicate pattern sharp/sharp	150 mm (6")
47.	SUBBC1577	JOSEPH Dissecting Scissors curved delicate pattern sharp/sharp	150 mm (6")
48.	SUBBC1600	KELLY Dissecting Scissors straight sharp/sharp	175 mm (6 7/8")
49.	SUBBC1611	KELLY Dissecting Scissors curved sharp/sharp	175 mm (6 7/8")
50.	SUBBC1622	KILNER Dissecting Scissors straight delicate pattern sharp/sharp	115 mm (4 1/2")
51.	SUBBC1633	LITTLER Dissecting Scissors curved eye for suture blunt/blunt	115 mm (4 1/2")
52.	SUBBC1644	Dissecting Scissors straight delicate pattern blunt/blunt	115 mm (4 1/2")
53.	SUBBC1655	Dissecting Scissors curved delicate pattern blunt/blunt	115 mm (4 1/2")
54.	SUBBC1666	KILNER Dissecting Scissors curved delicate pattern special flat blunt points	125 mm (5")
55.	SUBBC1688	KILNER Dissecting Scissors curved delicate pattern special flat blunt points	150 mm (6")
56.	SUBBC1700	STEVENS Tenotomy Scissors straight sharp/sharp	110 mm (4 1/4")
57.	SUBBC1711	STEVENS Tenotomy Scissors curved sharp/sharp	110 mm (4 1/4")
58.	SUBBC1100+A35:C65B35A35:C6A35:C64	Delicate Scissors straight sharp/sharp	110 mm (4 1/4")