



Device Material Assessment Form

DMA-20017a

Section 1 – Assessment Applicable to

Product Family:	Salter O2 Cannulas <i>* For Applicable Product Codes and/or SKU's, please see attached document (eg: EU Declaration of Conformity, SKU List, or etc.).</i>		
MDF #:	MDF-20017a	Date of Assessment:	17-SEPT-2021
TF #:	TF-20017a	DoC #	DOC-20017a

Section 2 – Materials Included

Article Description	Material
CONNECTOR, END P/N 205707, 205208, 205012	Polyvinyl Chloride (PVC) COMPLIANT
TUBE P/N 206004, 206014, 206025, 206007, 207001, 207004, 207007, 206016, 206407, 206030, 206001, 206009, 206050, 206010, 207014, 207015, 207020, 207025, 206002, 207010, 207050, 206020	Polyvinyl Chloride (PVC) COMPLIANT
TUBE P/N 205100, 205877, 205875, 205602	Polyvinyl Chloride (PVC) COMPLIANT
BOLO, CANNULA P/N 105020, 105223, 105603, 108331	Polyethylene (PE) COMPLIANT
CONECTOR, WYE P/N 205011, 205207	Polyvinyl Chloride (PVC) COMPLIANT
FACEPIECE P/N 205048	Polyvinyl Chloride (PVC) COMPLIANT



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<p>FACEPIECE P/N 205023, 205203, 205047, 205205, 205213, 205214, 205267, 205013, 205605, 205018, 205333, 105047</p>	<p>Polyvinyl Chloride (PVC) Tris(4-nonylphenyl, branched and linear) phosphite with $\geq 0.1\%$ w/w of 4-nonylphenol, branched and linear (TNPP) CAS 26523-78-4, $> 0 - < 1\%$ *REACH Candidate: Contains $\geq 0.1\%$, ($> 0 - < 1\%$)</p> <ul style="list-style-type: none"> ▪ Quantity of TNPP imported to EEA annually (non-COVID year): P/N's 205023, 205203, 205047, 205205, 205213, 205214, 205267, 205013, 205605, 205018, 205333, 105047 = 210.1 lbs. ▪ Exposure Risk Assessment in BRA-20017a. ▪ Explanation of continued safe use in BRA-20017a. <p>ADDITIONAL LABELING REQUIRED</p>
<p>TUBE P/N 207104, 205362, 207107, 205361</p>	<p>Polyvinyl Chloride (PVC) COMPLIANT</p>
<p>TUBE P/N 208330</p>	<p>Polyvinyl Chloride (PVC) COMPLIANT</p>
<p>TUBE P/N 206204, 206210, 206225, 206207, 206214, 206215, 206240, 206250, 207350</p>	<p>Polyvinyl Chloride (PVC) COMPLIANT</p>
<p>CONNECTOR, END P/N 205639, 205606</p>	<p>Polyvinyl Chloride (PVC) COMPLIANT</p>
<p>TUBE, CONNECTOR P/N 205069</p>	<p>Polyvinyl Chloride (PVC) COMPLIANT</p>
<p>CONNECTOR, END P/N 208136, 205732</p>	<p>Polyvinyl Chloride (PVC) COMPLIANT</p>
<p>CONNECTOR, END P/N 205359, 205449</p>	<p>Polyvinyl Chloride (PVC) COMPLIANT</p>
<p>CONNECTOR, WYE P/N 205215</p>	<p>Polyvinyl Chloride (PVC) COMPLIANT</p>
<p>LUER LOCK ADAPTER, FEMALE P/N 205745</p>	<p>Polyvinyl Chloride (PVC) COMPLIANT</p>
<p>TUBE P/N 105100</p>	<p>Polyvinyl Chloride (PVC) COMPLIANT</p>



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CONNECTOR P/N 105707	Polyvinyl Chloride (PVC) COMPLIANT
TUBE P/N 106030	Polyvinyl Chloride (PVC) COMPLIANT
TUBE P/N 208336, 206464, 206463	Polyvinyl Chloride (PVC) COMPLIANT
CONNECTOR, SWIVEL P/N 105757, 105758	High Density Polyethylene (HDPE) COMPLIANT
NIPPLE, NUT P/N 105480	Acrylonitrile-Butadiene-Styrene (ABS) COMPLIANT
E-Z WRAP P/N 105990, 108183, 105993	Foam: Polyethylene (PE) COMPLIANT
O-RING, SWIVEL CHANGE TO NEW MATERIAL P/N 105759	Silicone Rubber COMPLIANT
BIORIENTED POLYPROPYLENE FILM P/N 108401	Polypropylene COMPLIANT
METHYL ETHYL KETONE P/N 105161	Methyl Ethyl Ketone (MEK) COMPLIANT
ALCOHOL, ISOPROPYL P/N 105326	Alcohol, Isopropyl COMPLIANT

Section 3 – Materials Assessment



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Latex Assessment:	<p>The products listed in this assessment:</p> <ul style="list-style-type: none"><input checked="" type="checkbox"/> DO <u>NOT</u> contain natural rubber latex.<input checked="" type="checkbox"/> DO <u>NOT</u> use natural rubber latex in the manufacturing processes.<input checked="" type="checkbox"/> DO <u>NOT</u> use natural rubber latex in the packaging components or packaging adhesives used to ship our products. <ul style="list-style-type: none"><input type="checkbox"/> DO contain natural rubber latex.<input type="checkbox"/> DO use natural rubber latex in the manufacturing processes.<input type="checkbox"/> DO use natural rubber latex in the packaging components or packaging adhesives used to ship our products. <p>Comments:</p>
DEHP Assessment:	<p>The products listed in this assessment:</p> <ul style="list-style-type: none"><input checked="" type="checkbox"/> DO <u>NOT</u> contain DEHP. <ul style="list-style-type: none"><input type="checkbox"/> DO contain DEHP. <p>Comments:</p>
BPA Assessment:	<p>The products listed in this assessment:</p> <ul style="list-style-type: none"><input checked="" type="checkbox"/> DO <u>NOT</u> contain BPA. <ul style="list-style-type: none"><input type="checkbox"/> DO contain BPA. <p>Comments:</p>
REACH Assessment:	<p>The products listed in this assessment:</p> <ul style="list-style-type: none"><input type="checkbox"/> Exempt from REACH registration requirements.<input type="checkbox"/> REACH Compliant (No materials on list)<input checked="" type="checkbox"/> REACH Compliant (Materials on list.) <p>Comments: * P/N's 205023, 205203, 205047, 205205, 205213, 205214, 205267, 205013, 205605, 205018, 205333, 105047 REACH CL: Contains Tris(4-nonylphenyl, branched and linear) phosphite (TNPP) ≥ 0.1% w/w (0.1% - 1%) CAS 26523-78- 4 (See SKU list below for associated products).</p>



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<p>RoHS Assessment:</p>	<p>The products listed in this assessment:</p> <p><input checked="" type="checkbox"/> Outside Scope of RoHS requirements: This product family does not contain electrical or electronic components and does not depend on electric current or electromagnetic fields in order to work, therefore does not meet the definition of EEE contained in the directive. As such, the RoHS directive does not apply to this product family.</p> <p><input type="checkbox"/> RoHS Exempt</p> <p><input type="checkbox"/> RoHS Compliant (No materials on list)</p> <p><input type="checkbox"/> RoHS Compliant (Materials on list.)</p> <p>Comments:</p>
<p>Conflict Minerals Assessment:</p>	<p>The products listed in this assessment:</p> <p><input checked="" type="checkbox"/> Do <u>NOT</u> contain 3TG Conflict Minerals.</p> <p><input type="checkbox"/> Do contain 3TG Conflict Minerals (attach a summary and conclusion.)</p> <p>Comments:</p>
<p>EU MDR Restricted Materials, from Section 10.4.1</p>	<p>The products listed in this assessment:</p> <p><input checked="" type="checkbox"/> Do <u>NOT</u> contain EU MDR Section 10.4 Restricted Materials</p> <p><input type="checkbox"/> Do contain EU MDR Section 10.4 Restricted Materials</p> <p>Comments:</p>
<p>Medicinal Substances</p>	<p>The products listed in this assessment:</p> <p><input checked="" type="checkbox"/> DO <u>NOT</u> incorporate a medicinal substance.</p> <p><input type="checkbox"/> DO incorporate a medicinal substance.</p>
<p>Human Blood or Plasma</p>	<p>The products listed in this assessment:</p> <p><input checked="" type="checkbox"/> DO <u>NOT</u> incorporate human blood or plasma.</p> <p><input type="checkbox"/> DO incorporate human blood or plasma.</p>



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Tissues of Animal Origin	<p>The products listed in this assessment:</p> <p><input checked="" type="checkbox"/> DO <u>NOT</u> incorporate tissues of animal origin.</p> <p><input type="checkbox"/> DO incorporate tissues of animal origin.</p>
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Preparer Mark Armitage

Title Quality Engineer

Date 11/05/2021

Document approvals and revisions are contained within SunMed's eQMS system.

TNPP Associated SKUs:			
1651-7-50	M802433	13321	4805-5-5-25
SO-1186	C-102-4 (QTY 1)	E1611-7-50	4807-7-7-10
SO-1302	TC-102-4 (QTY 5)	M127222	4807-7-7-25
MI1300	C-102-7 (QTY 1)	1611TG-7-50	SO-405
1601-1-50	TC-102-7 (QTY 5)	SO-2101	4807TLC-7-7-25
1601-4-50	1616TLC-4-25	16SOFT-NEO-7-50	5017-7-7-25
1601-7-25-HC	1616TLC-7-25	16SOFTTG-NEO-7-50	5018-7-7-25
1601-7-50	M020447	BC2425-20	BC3780-20



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13322	M840514	SO-1974	SO-1977
E1601-7-50	5027-7-7-25	AMNC1001-25	4904-4-4-25
HSB02-S-NS-7-50	5028-7-7-25	BC2435-20	M043109
M121739	4824-4-4-25	SO-1975	4905-5-5-25
1601TG-7-50	4827-7-7-10	AMNC1002-25	4907-7-7-25
SO-2098	4827-7-7-25	BC2745-20	M043107
16SOFT-INF-7-50	MN1100A	SO-1976	M043108
16SOFTTG-INF-7-50	1610-7-25-HC	AMNC1003-25	MPS1500
1616-1-50	1610-7-50	MI1300B	SO-1462
1616-4-50	13320	1615-7-25-HC	1652-7-50
M3117	E1610-7-50	1615-7-50	1662-0-50
E1616-4-50	L1610-7-50	13323	1602-1-50
M127898	1610TG-7-50	HSB02-S-KK-7-50	1602-10-50
1616-7-50	M127221	M125077	1602-14-50
SO-1956	SO-2100	16SOFT-TOD-7-50	1602-25-25
SO-1957	16SOFT-PRE-7-50	4804-4-4-10	1602-4-50
13309	16SOFTTG-PRE-7-50	4804-4-4-25	1602-7-50
M3115	MN1100B	E4804-4-4-25	13324
E1616-7-50	SO-1460	M838152	E1602-7-50
HSB02-S-LF-7-50	1611-7-10	SO-404	HSB02-S-K-7-50
M124784	1611-7-25-HC	4804TLC-4-4-10	L1602-7-50
1616TG-7-50	1611-7-50	4804TLC-4-4-25	M121831
SO-1481	SO-1902	SO-1905	SO-1497
SO-1507	SO-1508	SO-1525	SO-1532
SO-1536	SO-1547	SO-1548	SO-1566

TNPP Associated SKUs:			
1602-7-25	SO-1327	1600-12-50	2252G-25-10
1602-9-50	SO-1353	1600-14-50	2402G-40-10
1602TG-7-50	SO-1167	1600-15-50	SO-1308
SO-2073	SO-1231	1600-16-50	SO-1333
SO-2099	SO-1457	M124052	SO-1338
SO-1387	2502-50-25	1600-20-25	SO-1339
16SOFT-PED-4-50	E1606-0-50	1600-21-25	SO-1343
16SOFT-PED-7-50	M122391	1600-24-25	SO-1348
1602TLC-7-25	1606B-0-50	1600-25-25	SO-1352



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16SOFTTG-PED-7-50	SO-1372	M121845	SO-1357
16SOFT-PED-14-50	SO-1381	1600-3-50	SO-1380
16SOFTTG-PED-14-50	SO-1384	1600-30-20	SO-1385
M038098	SO-1286	1600-35-20	SO-1444
13304	SO-1855	1600-4-50	M839638
13307	SO-1857	SO-1573	SO-1122
1650-20-25	SO-1456	SO-504	SO-1142
1650-4-50	SO-500	SO-1671	SO-1178
1650-7-50	SO-1658	SO-1691	SO-1208
13310	SO-1659	SO-1951	SO-1209
M122695	SO-1695	SO-1986	SO-1230
1699-10-50	SO-1817	SO-1996-5	SO-1247
1699-14-50	SO-1834	SO-2045	SO-1252
1699-20-25	HCKIT-06-06-25-10	M128003	SO-1269
1699-25-25	HCKIT-06-06-50-10	1600-40-20	SO-1282
1699-50-20	SO-2013	1600-5-50	SO-1284
1699-7-50	SO-2014	M010637	SO-1852
13301	SO-2081	1600-50-20	SO-1853
1606-0-50	1600-1-50	1600-7-50	SO-1862
SO-1316	M001506	SO-519	SO-1454
SO-1319	1600-10-50	SO-1700	SO-1475
SO-1572	SO-1613	SO-1662	SO-602
SO-392	SO-1646	SO-1674	SO-606
SO-1595	SO-503	SO-562	SO-607
SO-1608	SO-1661	SO-564	SO-1676

TNPP Associated SKUs:			
SO-1682	13300	M016477	00-04340-00-01
SO-1683	1005255	16SOFT-7-50	SO-1979
SO-1690	M3120	SO-1332	SO-1980
SO-1696	E1600-7-50	SO-1366	SO-1998
SO-612	HSB02-S-7-50	SO-1368	SO-1999
SO-629	L1600-7-50	SO-1103	SO-2000
SO-639	SL1600-7-50	SO-1270	SO-2010
SO-1722	M121738	SO-1285	SO-2087
SO-729	1600-9-50	SO-1450	SO-2169



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SO-756	1600G-10-50	SO-1458	SO-2170
SO-797	1600G-25-25	SO-1472	SO-2175
SO-1750	M122838	SO-1910	M049562
SO-1763	SO-292	SO-1570	16SOFT-4-50
SO-1779	SO-406	SO-1582	SO-1315
SO-1808	SO-1860	SO-1594	SO-1113
SO-1840	SO-1945	SO-1637	SO-1250
SO-1844	1699G-10-50	SO-516	SO-656
SO-1925	SO-2074-200	SO-1666	HCKIT-01-06-25-5
SO-1952	SO-2097	SO-1667	HCKIT-01-06-50-5
SO-1960	1699TLC-7-25	SO-594	HCKIT-01-02-25-10
SO-1961	1600TLC-1-25	SO-610	HCKIT-01-02-50-10
SO-2001	1600TLC-14-25	SO-660	HCKIT-02-06-25-10
SO-2002	1600TLC-15-25	SO-1759	HCKIT-02-06-50-10
M050706	1600TLC-21-25	SO-1936	HCKIT-02-02-25-10
SO-1941	1600TLC-25-25	22GSOFT-25-10	HCKIT-02-02-50-10
SO-2037	1600TLC-4-25	SO-1948	HCKIT-04-06-25-10
SO-2042	1600TLC-7-25	SO-1949	HCKIT-04-02-25-10
SO-2043	SO-1123	HCKIT-04-06-50-10	00-05088-00-01
SO-2048	SO-1498	HCKIT-04-02-50-10	SO-2008
SO-2055-25	SO-1740	SO-1958	SO-2128
SO-2076	1606BTLC-0-25	SO-1955	16SOFT-14-50
SO-2091	1606TLC-0-25	SO-1959	SO-2011
SO-2092	1600GTLC-14-25	SO-1969	16SOFT-25-25
SO-2177	1600GTLC-7-25	SO-1970	00-05089-00-01

TNPP Associated SKUs:			
16SOFT-0-50.	1650Q-7-50	1650HF-50-10	SOLO1300
SO-1997	1606Q-0-50	1600HF-14-10	SOLO1300-EV-5
16SOFT-B-0-50	C-103-4 (QTY 1)	1600HF-14-25	MP1500
16SOFT-B-0-50.	TC-103-7 (QTY 5)	7914-14-10	MP1500-BR
SO-1954	C-103-7 (QTY 1)	1600HF-15-25	5023-7-25
C-101-4 (QTY 1)	SO-2102	1600HF-25-10	5024-7-25
TC-101-4 (QTY 5)	SO-2122	7925-25-10	5009-7-7-25
C-101-7 (QTY 1)	1600QTLC-7-25	1600HF-4-25	5010-7-7-25
TC-101-7 (QTY 5)	MA1700	SO-1983	5033-7-25



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16SOFT-2-50	SO-1463	1600HF-4-10	5011-1-25
16SOFT-1-50.	16SOFT-HF-7-25	M010901	5011-2-25
16SOFTTG-14-50	79SOFT-7-25	M014158	5011-7-25
16SOFTTG-7-50	16SOFT-HF-14-25	M014159	5500
16SOFTTG-25-25	79SOFT-14-25	M014534	5012-1-25
SO-292-S-50	SO-1950	SO-1291	5012-1-50
SO-2060	16SOFT-HF-25-10	SO-1292	5012-7-25
SO-2069	79SOFT-25-10	HSB02-S-HF-7-25	SO-1964
SO-2071	16SOFTTG-HF-7-25	1600HFTLC-14-25	SO-1971
SO-2072	16SOFTTG-HF-14-25	7914TLC-14-25	5012-2-25
SO-2085	16SOFTTG-HF-25-10	1600HFTLC-25-10	SO-1314
SO-2086	1600HF-40-10	1600HFTLC-7-25	SO-1990
1600Q-25-25	1600HF-50-10	7907TLC-7-25	5013-7-25
00-01843-00	1600HF-7-10	MA1700-BR	5014-7-25
1600Q-4-50	SO-1681	C-104-4 (QTY 1)	5015-7-25
1600Q-50-20	1600HF-7-25	TC-104-4 (QTY 5)	5016-7-25
1600Q-7-25	7907-7-10	C-104-6 (QTY 1)	5004-7-25
1600Q-7-50	SO-1680	TC-104-6 (QTY 5)	5003-7-25
SO-741	SO-2044	17ALOFT-4-50.	5007-7-7-25
00-01844-00	SO-2049	17ALOFT-6-50.	5001-7-25
13308	SO-2052	1700-6-50	5002-7-25
M3110	SO-2173	1700-4-50	1233-0-10
HSB02-S-Q-7-50	SO-2176	BC2755-20	1301-0-10
M128348	SO-1290	AMNC1004-25	1301-0-25

TNPP Associated SKUs:			
8960-PEP-7-25	5052-7-7-25	5022-7-25	5751-7-25
1302-0-10	5055-7-7-25	5037-7-25	5700-0-1
1302-0-25	5056-7-7-25	5038-7-25	5700A3-0-1
8672-7	5045-7-7-25	5005-2-25	5700A5-0-1
5041-7-7-25	5047-7-7-25	5005-7-25	5700E-0-1
5042-7-7-25	5006-7-25	5006-1-25	5700EK-0-1
SO-1966	5700P-0-1	5006-2-25	5700EK-2-0-1
5049-7-7-25	5700PA5-0-1	SO-2012	5700S20-0-1
5050-7-7-25	5700PE-0-1	SO-2053-25	5760-7-25



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5053-7-7-25	5700PEK-0-1	SO-2054-25	5761-2-25
5054-7-7-25	5700PEK-2-0-1	5750-7-25	5761-7-25
5043-7-7-25	5700PA3-0-1	5751-2-25	5036-7-25
5044-7-7-25	5700PS20-0-1	5700CK-2-0-1	SO-1461
5051-7-7-25	5021-7-25	1216-0	1053TLC-14
1053-25	1053-4	1053-7	1053TLC-14-25
1053-25-25	1053-4-50	1053-7-50	1056-1
1053TLC-7	1056-4	1056-7	1056-1-50
1053TLC-7-25	1056-4-50	1056-7-50	1057TLC-0
1057-0	1057B-0	1063-16	1057TLC-0-25
1057-0-50	1057B-0-50	1063-16-50	1600-2
1600G-10	1600Q-50	1601Q-7	1600-2-50
1600-G-10-50	1600Q-4-50	1601Q-7-50	1600TLC-50
1616-3	1650-10	1650-14	1600TLC-50-20
1616-3-50	1650-10-50	1650-14-50	1601-4
1650-15	1650-25	1650-50	1601-4-25
1650-15-50	1650-25-25	1650-50-20	1601-4-50
1699-12	251-5030	B-701931-00 (SO 404)	1699TLC-10
1699-12-50	251-5030-50	DR1161 (SO-1967)	1699G-10-25
DM6100 (SO-2053)	L1601-7	DM7100 (SO-2054)	1699TLC-10-50
DM5500-25 (SO-2053)	L1600-7-50	DM7100-25 (SO-2054)	