



**DECLARATION OF CONFORMITY**

**TF1005 Oxygen Cannulas**

**Salter Labs  
30 Spur Drive  
El Paso, Texas 79906  
USA**

Product Name: **Oxygen Cannulas & Accessories**  
Model Number or Designator: See attached  
Control Designator: **TF1005** 27-October-2017  
Device Classification: Class IIa, Rule 2, per Annex IX of the European Medical Device Directive (93/42/EEC).  
Accessories: Class I by Annex IX, Rule 1  
  
Global Medical Device Nomenclature Code (GMDN): **35201**, Basic nasal oxygen cannula.  
Universal Medical Device Nomenclature System (UMDNS): **12700**, Cannulae, Nasal Oxygen  
Product Options/Accessories: N/A

**The object of the declaration described is in conformity with the provisions of Council Directive: 93/42/EEC (Medical Devices Directive), Annex II 3.2.**

The Manufacturer is certified by the Notified Body listed below to EN ISO 13485:2012 and Annex II excluding section four (4) of the Medical Device Directive.

**EC Certificate Number:** **CE 608598**. Expiry Date: 20-February-2022

**Notified Body:** BSI Group  
Kitemark Court, Davy Avenue  
Knowlhill, Milton Keynes  
MK5 8 PP  
United Kingdom

**Authorized EU Representative:** MT Promedt Consulting GmbH  
Altenhofstrasse 80  
66386 St. Ingbert  
Germany

Revision: **N**

Signature: 

Date of Issue: 27-October-2017

Printed Name: Peggy Collins

Place of Issue: Regulatory Office, Salter Labs  
Carlsbad, California, USA

Title: Regulatory Affairs



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<b>Model #</b>	<b>Model Description</b>
00-01843-00	Patient Kit- (5) #1600Q-25
00-01844-00	Patient Kit- (10) #1600Q-7
00-05088-00-01-0	Patient kit - (5) 16soft-4
00-05089-00-01-0	Patient kit - (5) 16soft-25
1053-25	Cannula, adult conventional, oxygen w/3-channel tube 25'
1005255	Nasal Cannula (Adult) Salter Style with 7' (2.1 m) supply tube.
1053-4	Cannula, adult conventional, oxygen w/3-channel tube 4'
1053-7	Cannula, adult conventional, oxygen w/3-channel tube 7'
1053-25	Cannula, adult conventional, oxygen w/3-channel tube 25'
1053TLC-14	Cannula, adult conventional, oxygen w/3-channel tube 14' and E-Z Wrap
1053TLC-7	Cannula, adult conventional, oxygen w/3-channel tube 7' and E-Z Wrap
1056-10	Cannula, adult conventional, oxygen w/smooth bore tube 10'
1056-1	Cannula, adult conventional, oxygen w/smooth bore tube 1'
1056-4	Cannula, adult conventional, oxygen w/smooth bore tube 4'
1056-7	Cannula, adult conventional, oxygen w/smooth bore tube 7'
1057-0	Cannula, adult conventional, oxygen w/out tube
1057B-0	Cannula, Adult conventional oxygen without tube-
1057TLC-0	Cannula, adult, oxygen with E-Z Wraps
1063-16	Cannula, adult conventional, oxygen w/3-channel tube, 16'
1068-16	Cannula, adult conventional, oxygen w/smooth bore tube, 16'
13300	Nasal Cannula (Adult) Salter Style with 7' (2.1 m) supply tube
13301	Nasal Cannula (adult) Salter Style with 7' (2.1 m) O2 supply tube, female thread grip connector.
13304	Nasal Cannula (adult) Salter Style with 14' (4.3 m) supply tube.
13307	Nasal Cannula (adult) Salter Style with 30' (9.1 m) supply tube.
13308	Nasal Cannula (Adult) Salter Style with 7' (2.1 m) supply tube for oxygen flows up to 8 LPM.
13309	Nasal Cannula (Adult) Salter Style with 7' (2.1 m) supply tube micro cannula for flows up to 3 LPM.
13310	Nasal Cannula (Adult) Salter Style with 7' (2.1 m) supply tube.
13320	Nasal Cannula (Premature) Salter Style with 7' (2.1 m) supply tube.
13321	Nasal Cannula (Neonate) Salter Style with 7' (2.1 m) supply tube.
13322	Nasal Cannula (Infant) Salter Style with 7' (2.1 m) supply tube.
13323	Nasal Cannula (Intermediate Infant) Salter Style with 7' (2.1 m) supply tube.
13324	Nasal Cannula (Pediatric) Salter Style with 7' (2.1 m) supply tube.
1600-1	Cannula, adult, oxygen w/3-channel tube 1'
1600-10	Cannula, adult, oxygen w/3-channel tube 10'



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<b>Model #</b>	<b>Model Description</b>
1600-12	Cannula, adult, oxygen w/3-channel tube 12'
1600-13	Cannula, adult, oxygen w/3-channel tube 13'
1600-14	Cannula, adult, oxygen w/3-channel tube 14'
1600-15	Cannula, adult, oxygen w/3-channel tube 15'
1600-16	Cannula, adult, oxygen w/3-channel tube 16'
1600-2	Cannula, adult, oxygen w/3-channel tube 2'
1600-20	Cannula, adult, oxygen w/3-channel tube 20'
1600-21	Cannula, adult, oxygen w/3-channel tube 21'
1600-24	Cannula, adult, oxygen w/3-channel tube 24'
1600-25	Cannula, adult, oxygen w/3-channel tube 25'
1600-3	Cannula, adult, oxygen w/3-channel tube 3'
1600-30	Cannula, adult, oxygen w/3-channel tube 30'
1600-35	Cannula, adult, oxygen w/3-channel tube 35'
1600-4	Cannula, adult, oxygen w/3-channel tube 4'
1600-40	Cannula, adult, oxygen w/3-channel tube 40'
1600-5	Cannula, adult, oxygen w/3-channel tube 5'
1600-50	Cannula, adult, oxygen w/3-channel tube 50'
1600-7	Cannula, adult, oxygen w/3-channel tube 7'
1600-9	Cannula, adult, oxygen w/3-channel tube 9'
1600G-10	Cannula, adult, oxygen w/3-channel tube 10'
1600G-25	Cannula, adult, oxygen w/3-channel tube 25'
1600GTLC-14	Cannula (adult) with 14' 3-channel tube (green) and EZ Wraps
1600GTLC-7	Cannula, adult, oxygen w/3-channel tube 7' (green) with E-Z Wraps
1600HF-14	Cannula, adult, high flow, oxygen w/3-channel tube 14'
1600HF-15	Cannula, adult, high flow, oxygen w/3-channel tube 15'
1600HF-25	Cannula, adult, high flow, oxygen w/3-channel tube 25'
1600HF-40	Cannula, adult, high flow, oxygen w/3-channel tube 40'
1600HF-4	Cannula, adult, high flow, oxygen w/3-channel tube 4'
1600HF-50	Cannula, adult, high flow, oxygen w/3-channel tube 50'
1600HF-7	Cannula, adult, high flow, oxygen w/3-channel tube 7'
1600HFTLC-14	Cannula (high flow), Adult 14' 3-channel tube w/ E-Z wraps
1600HFTLC-25	Cannula (high flow), Adult 25' 3-channel tube w/ E-Z wraps
1600Q-14	Cannula, adult, oxygen w/3-channel tube 14', and extra-large face piece
1600Q-25	Cannula, adult, oxygen w/3-channel tube 25', and extra-large face piece
1600Q-4	Cannula, adult, oxygen w/3-channel tube 4', and extra-large face piece
1600Q-50	Cannula, adult, oxygen w/3-channel tube 50', and extra-large face piece



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Table with 2 columns: Model # and Model Description. It lists various cannula models such as 1600Q-7, 1600TLC-1, 1601-1, 1602-10, etc., with their corresponding descriptions.



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<b>Model #</b>	<b>Model Description</b>
1615-7-HC	Cannula, intermediate infant, oxygen, w/3-channel tube, 7'
1615-7	Cannula, intermediate infant, oxygen, w/3-channel tube, 7'
1616-1	Cannula, adult, oxygen low flow w/3-channel tube, 1'
1616-3	Cannula, adult, oxygen low flow w/3-channel tube, 3'
1616-4	Cannula, adult, oxygen low flow w/3-channel tube, 4'
1616-7	Cannula, adult, oxygen low flow w/3-channel tube, 7'
1616TG-7	Cannula, adult, oxygen low flow w/3-channel tube, 7' and female thread grip
1616TLC-4	Cannula, adult, oxygen low flow w/3-channel tube, 4' with E-Z Wraps
1616TLC-7	Cannula, adult, oxygen low flow w/3-channel tube, 7' with E-Z Wraps
1650-10	Cannula, adult, oxygen w/smooth bore tube 10'
1650-14	Cannula, adult, oxygen w/smooth bore tube 14'
1650-15	Cannula, adult, oxygen w/smooth bore tube 15'
1650-20	Cannula, adult, oxygen w/smooth bore tube 20'
1650-25	Cannula, adult, oxygen w/smooth bore tube 25'
1650-4	Cannula, adult, oxygen w/smooth bore tube 4'
1650-50	Cannula, adult, oxygen w/smooth bore tube 50'
1650-7	Cannula, adult, oxygen w/smooth bore tube 7'
1650HF-50	Cannula, adult, high flow, oxygen w/smooth bore tube 50'
1650Q-7	Cannula, adult, oxygen, extra-large face piece, w/smooth bore tube 7'
1651-7	Cannula, infant, oxygen w/smooth bore tube 7' and extra-large face piece
1652-7	Cannula, pediatric, oxygen w/smooth bore tube 7'
1662-0	Cannula, pediatric, oxygen w/out tube
1699-10	Cannula, adult, oxygen w/3-channel tube 10', and female thread grip connector
1699-12	Cannula, adult, oxygen w/3-channel tube 12', and female thread grip connector
1699-14	Cannula, adult, oxygen w/3-channel tube 14', and female thread grip connector
1699-20	Cannula, adult, oxygen w/3-channel tube 20', and female thread grip connector
1699-25	Cannula, adult, oxygen w/3-channel tube 25', and female thread grip connector
1699-50	Cannula, adult, oxygen w/3-channel tube 50', and female thread grip connector
1699-7	Cannula, adult, oxygen w/3-channel tube 7', and female thread grip connector
1699G-10	Cannula, adult, oxygen w/3-channel tube 10', and female thread grip connector
1699TLC-10	Cannula, adult, oxygen, w/3-channel tube 10' and e-z wraps with thread grip
1699TLC-7	Cannula, adult, oxygen w/3-channel tube 7' and E-Z Wraps with thread grip
16SOFT-0	Nasal Cannula (Adult) Salter Style without supply tube. Non-DEHP
16SOFT-1	Cannula, adult nasal with 1'3 channel tube
16SOFT-2	Cannula, adult nasal with 2' 3-channel tube
16SOFT-4	Cannula, adult nasal with 4' 3-channel tube



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<b>Model #</b>	<b>Model Description</b>
16SOFT-7	Cannula, adult nasal with 7' 3-Channel Tube
16SOFT-14	Cannula, adult nasal with 14' 3-channel tube
16SOFT-25	Cannula, adult nasal with 25' 3-channel tube
16SOFT-B-0	Cannula, adult nasal, Salter Style without supply tube. Non-DEHP
16SOFT-HF-14	Adult nasal cannula with 14' 3-channel tube
16SOFT-HF-25	Adult nasal cannula with 25' 3-channel tube
16SOFT-HF-7	Adult Nasal Cannula with 7' 3-Channel Tube
16SOFT-PED-14	Salter Style Nasal O2 Cannula (Pediatric), 4' (1.2 m) 0 to 6 LMP, Non DEHP
16SOFT-PED-4	Salter Style Nasal O2 Cannula (Pediatric), 14' (4.3 m) 0 to 6 LMP, Non DEHP
16SOFT-PED-7	Salter Style Nasal O2 Cannula (Pediatric), 7' (2.1 m) 0 to 6 LMP, Non DEHP
16SOFTTG-14	Cannula, adult nasal, with 14' 3-channel tube with ThreadGrip
16SOFTTG-25	Cannula, adult with 25' 3-channel tube with Thread Grip
16SOFTTG-7	Cannula, adult, with 7' 3-channel tube
16SOFTTG-HF-14	Cannula, adult, with 14' 3-channel tube with ThreadGrip
16SOFTTG-HF-25	Cannula, adult nasal, with 25' 3-channel tube with thread grip
16SOFTTG-HF-7	Cannula, adult high flow oxygen w/3-channel tube 7' (soft) with female ThreadGrip connection
16SOFTTG-PED-14	Cannula, Pediatric, Oxygen w/3-Channel Tube 14'(Soft) with female ThreadGrip connection
16SOFTTG-PED-7	Cannula, Pediatric, oxygen w/3-channel tube 7'(soft), 50/cs with Threaded Grip-
1700-4	Cannula, adult nasal with 4' 3-channel tube
1700-6	Cannula, adult nasal with 6' 3-channel tube
17ALOFT-4	Cannula, adult nasal with 4' 3-channel tube
17ALOFT-6	Cannula, adult nasal with 6' 3-channel tube
22GSOFT-25	Convenience kit-(1) #1205, (1) #1220, (6) #16soft-7, (1) #2025g, (2) #851549
2252G-25	Convenience Kit- (1) #1205, (1) #1220, (6) #1600-7 (1) 2025G, (2) #851549
2402G-40	Cannula Convenience Kit- (2) #1205, (2) #1215, (6) #1600, (1) 2040G, (1) #851549
251-5030	Nasal Cannula (Adult) with 7' (2.1 m) supply tube
4801-2	Cannula, adult, dual oral/nasal CO2 sample with oral form wire, 2' line w/male luer slip connector
4804-4-4	Cannula, adult, demand w/4' supply tube
4804-4-4	Cannula, adult, demand, w/4' supply tube
4804TLC-4-4	Cannula, adult, demand, w/4' supply tube with E-Z Wraps
4805-5-5	Cannula, adult, demand, w/5' supply tube
4805TLC-5-5	Cannula, adult, demand, w/5' supply tube with E-Z Wraps
4807-7-7	Cannula, adult, demand w/7' supply tube
4807TLC-7-7	Cannula, adult, demand, w/7' supply tube with E-Z Wraps
4824-4-4	Cannula, pediatric, demand, w/4' supply tube



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4827-7-7	Cannula, pediatric, demand, w/7' supply tube
4904-4-4	Demand Nasal Cannula, Adult w/ 4' tube
4905-5-5	Demand Nasal Cannula, Adult w/ 5' tube
4907-7-7	Demand Nasal Cannula, Adult w/ 7' tube
AHC-0	Cannula, adult head
AR-1600-7	Cannula, adult, oxygen w/3-channel tube 7'
L1600-7	Cannula, adult, oxygen w/3-channel tube 7'
L1602-7	Cannula, pediatric, oxygen w/3-channel tube 7'
L1610-7	Cannula, premature, oxygen w/3-channel tube 7'
L1611-7	Cannula, neonate, oxygen w/3-channel tube 7'
M3110	Cannula, adult, oxygen w/3-channel tube 7', and extra-large face piece
M3115	Cannula, adult, oxygen low flow w/3-channel tube, 7'
M3117	Cannula, adult, oxygen low flow w/3-channel tube, 4'
M3120	Cannula, adult, oxygen w/3-channel tube 7'
M3121	Cannula, pediatric, oxygen, w/3-channel tube, 7'
M3122	Cannula, infant, oxygen w/3-channel tube 7'
SL1600-7	Cannula, adult, oxygen w/3-channel tube 7'
SO-1388	Cannula, infant, oxygen w/3-channel tube 2"
SO-1389	Cannula, neonate, oxygen w/3-channel tube 2"
SO-1390	Cannula, intermediate infant, oxygen w/3-channel tube 2"
SO-1923	Patient Kit- (2) #1220, (12) #1600, (2) #2025, (1) #851549
SO-1945	Cannula, Adult, Oxygen w/ 3 channel tube 7'
SO-1964	Cannula, adult sensor with 7' tube
SO-1966	Cannula, adult w/two 7' lines w/nasal sampling w/male luer-lock connector & filter
SO-1967	Cannula, adult conventional, oxygen w/3-channel tube 7'
SO-1974	Cannula, Premature, Oxygen with 1" tube
SO-1975	Cannula, Neonatal, Oxygen with 1" tube
SO-1976	Cannula, Infant, Oxygen with 1" tube,
SO-1977	Cannula, Pediatric, Oxygen with 1" tube,
SO-2053	Adult Sensor Cannula with 7' tube
SO-2054	Adult Sensor Cannula with 7' tube
SO-2055	Patient kit (6) - #1600-7, (1) - #2025g-25, (1)- #2040g-40, 25/cs,(2)#1248-0-5
SO-404	Cannula, adult, demand, w/4' supply tube
SO-405	Cannula, adult, demand, w/7' supply tube
SO-406	Cannula, adult, oxygen w/3-channel tube 7' and std. end connector
SO-426-14-14	Cannula, intermediate infant, divided w/14' O2 line and 14' CO2 line w/female luer-lock connector



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SO-292-S	Cannula, adult, oxygen, w/3-channel tube 7'
SO-2074	Cannula adult, nasal, with 3-channel 7-foot tube

<b>Model #</b>	<b>Class I Cannula Accessories</b>
1232-0	Nose Clip