

IFU/LABELING SPECIFICATION AND CHANGE CONTROL FORM



CONSUMABLE GROUP QUALITY SYSTEM – MULTI-USE FORM

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Details of Change			
Labeling Action Types	<input checked="" type="checkbox"/> Change <input type="checkbox"/> New <input type="checkbox"/> Cancellation		
Product Name	SureSmile VPro Mouthpiece		
Product SKU #	V18102		
Labeling #	PRT-10176		
Revision	4		
Labeling Title	Label, Finished, SureSmile VPro Mouthpiece		
Change Initiator / Date	Hannah Gurnavage / February 22, 2022		
Change Control / Change Order Number (if already available)	CHANGE-PLN-2021-521		
Description of Change (What is changing?)	<input type="checkbox"/> New item? If not, please describe: Spelling error and translation error being corrected		
Reason / Justification for Change (Why?) If applicable: CC- CHANGE-PLN-2021-521 <input type="checkbox"/> N/A	Spelling, grammar and translation issues being corrected. CE mark being removed along with MD, WEEE, and CE icons and EC and CH Reqs.		
Labeling Type	<input checked="" type="checkbox"/> Packaging	<input type="checkbox"/> IFUs-Manuals/Symbol list <input type="checkbox"/> Safety Data Sheet (SDS)-R&D?	<input type="checkbox"/> Marketing Communications / Advertising <input type="checkbox"/> Tip cards- Technical Guide-Getting Started Guide
Approval Panel "LRC" Members? <i>as defined in 8000-SOP-007</i>	Name/ Function(s): Khyati Dave, Ray Woodyard, Hannah Gurnavage, Kathryn Rowley, Chad Jones, Ken Guaragno.		
Additional Notification Panel Members Required?	Name/ Function(s):		
IFU/Labeling Material Specifications and Implementation Point			
Implementation Point <input type="checkbox"/> New <input type="checkbox"/> Immediate - Scrap existing inventory. <u>Existing inventory cannot be used.</u> <input type="checkbox"/> Use Up Stock all existing labeling, Until date ex: 6 months <input type="checkbox"/> e-IFU website update <input type="checkbox"/> Re-work existing products or labeling or IFU <input checked="" type="checkbox"/> Other, Describe: Label PRT-10255, PRT-10176, and IFU PRT-10238 are to be implemented at the same time upon arrival <input type="checkbox"/> IFU- European multilingual-> <i>as defined in 8000-FM-007-05</i> <input type="checkbox"/> IFU- Non-European multilingual: -> <i>as defined in 8000-FM-007-05</i> <input type="checkbox"/> IFU- Website Use Up, until date ex: 6 months			
Printing specifications <input type="checkbox"/> Specified in ERP System <input type="checkbox"/> Specified in Controlled Document: site specific specification # <input type="checkbox"/> N/A (Artwork not intended for printing) <input checked="" type="checkbox"/> Label Specifications required (answer questions below)			
Trim Size	4" x 5"	Finished Size (Label, Packaging, IFU folded)	4" x 5"
Varnish	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	Binding <input type="checkbox"/> Corner <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Stapled <input type="checkbox"/> Other <input type="checkbox"/> Booklet (Saddle Stitched)
Specialty	<input type="checkbox"/> Spot	<input checked="" type="checkbox"/> Flood	
Ink/Colors	PMS 3005C, PMS 425C, Black	Bleeds	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
# of Folds	<input checked="" type="checkbox"/> N/A	Single or Double Sided	<input checked="" type="checkbox"/> Single Sided <input type="checkbox"/> Double Sided
Stock	White semi-gloss with perm adhesive flood coat TT printable full varnish		
Other	<ul style="list-style-type: none"> • Magenta color indicates variable information to be imprinted at manufacturing site 		

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- HIBC Data Matrix 2D Barcode to contain: LIC No. (D001), Reorder No. (V18102), UOM (1), Lot Number, and Manufacturing Date. Human readable version of this information to be printed below the data matrix.

- For small runs, digital printing, which uses CMYK interpretation of the PMS colors, is acceptable. The inks are UV curable and don't require varnish.
- Quantity per roll = 1000
- Packing List and C of C required with the expiration date

IFU Finished Size (Folded)

 Specified Symbol -> **Following 8000-FM-007-02** Specified Address -> **Following 8000-FM-007-03****1.0 REFERENCES**

8000-SOP-007 - Labeling procedure

8000-SOP-005 – IFU Requirements Procedure

FORM NO	8000-FM-007-01	REVISION LEVEL	1
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SureSmile® VPro™

Mouthpiece

Boquilla | Peça bucal | Moldiera | L'embout buccal
 Bite dentale | Mundstück | Mondstuk | Munnstykket | Mundstykket
 Munstycket | Suukappale | Munnstykki | Ustnik

REF V18102



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 Australia



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 6DYYYMMDDC

LOT XXXXXXXXXXXXX

YYYY-MM-DD

Representante Autorizado Brasileiro

Importado por:

NXT DISTRIBUIDORA E SERVIÇOS LTDA
 CPNJ: 24.921.557/0001-23
 Av. Independência, 925 sala 1314,
 Bairro Independência - Porto Alegre/RS
 CEP 90035-076

ANVISA número 81774499001

Technical Responsible:

Daniel Souza Pinto Ramos CRO-RS 12.185



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