



PACKAGING SPECIFICATIONS

00770 47 138 rev 00

Creation date: 29/11/2022

Revision date: N/A



Vial 10ml ISO in molded glass type 1 in TRAY

Clear version, Cold treatment

SGD Pharma reference: [00770 47 138](#)

Bare glass Manufacturing site: SGD Pharma Saint-Quentin-Lamotte

Sterilization Process: Washing with WFI, depyrogenation, final sterilization by EtO

1. Vials specification

Technical drawing: [Appendix 1](#)

Mold number	00770
Nominal capacity	10 ml
Brimful capacity	15 ml
Neck Finish	ISO 20
Approx. Weight	21 g
Height	53.5 mm
Ø	25.4 mm

2. Tray Specification

Primary packaging type	Tray
Material	Tray: Polypropylene (PP) Finish Position: Downward (USD) Tray sheet: PE-HD fibers (Tyvek®) Tray Lid: PE-HD fibers and thermosetting adhesive (Tyvek®)
Dimensions	379 x 221 x h63.5 mm
Net weight	1.68 kg
Gross weight	2.01 kg
Vials per Tray	80
Tray per layer	2

3. Secondary packaging

Scheme: **Appendix 2**

Steribag

Material	PE-HD fibers (Tyvek®) / HDPE
Bag composition	Double
Tyvek® Format	Header bag

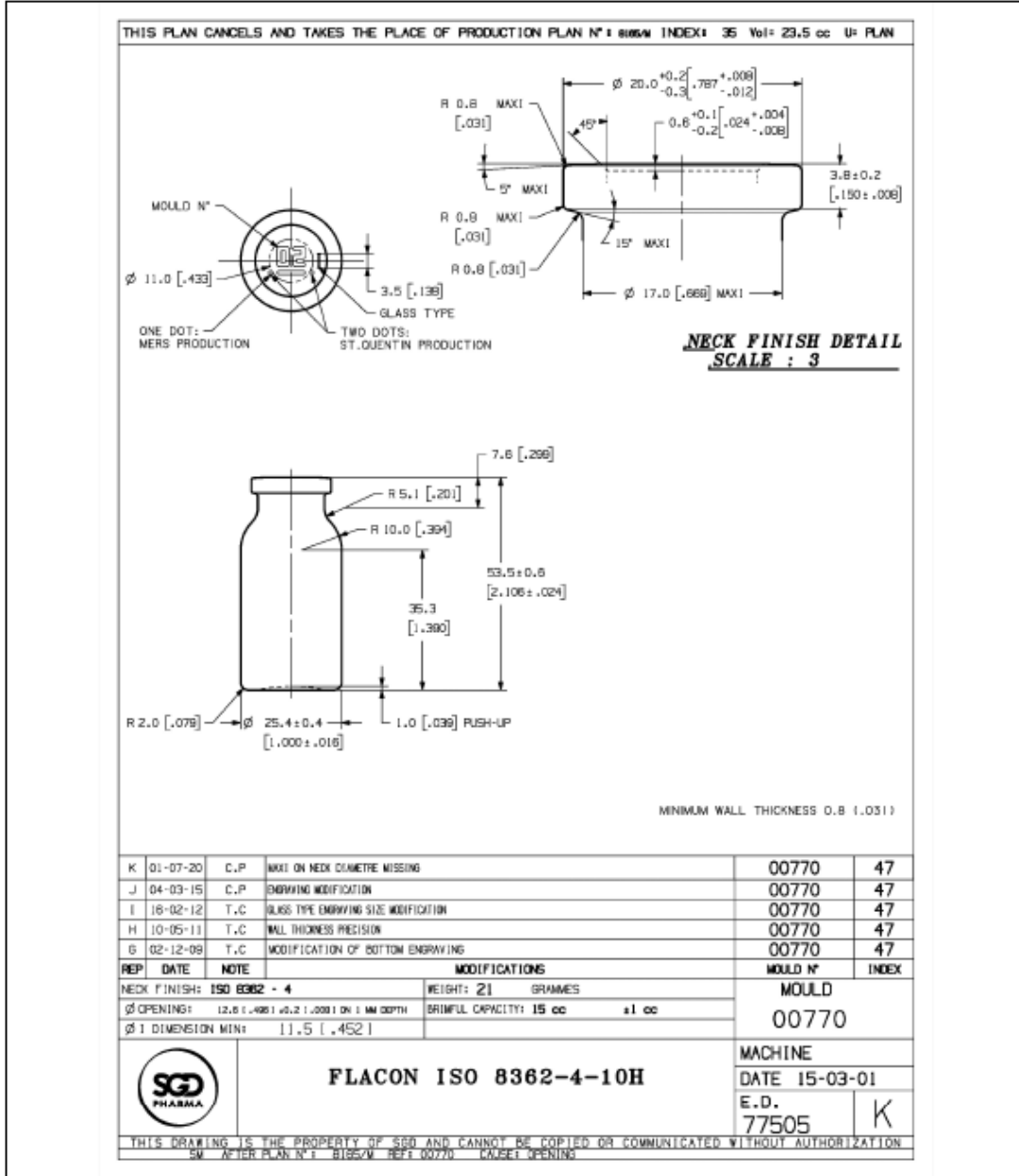
Box

Material	Alveolar PP
Dimension	788 x 235 x h345 mm
Net weight	13.4 kg
Gross weight	17.26 kg
Layer per box	4
Vials per box	640
Boxes per layer	5

Pallet

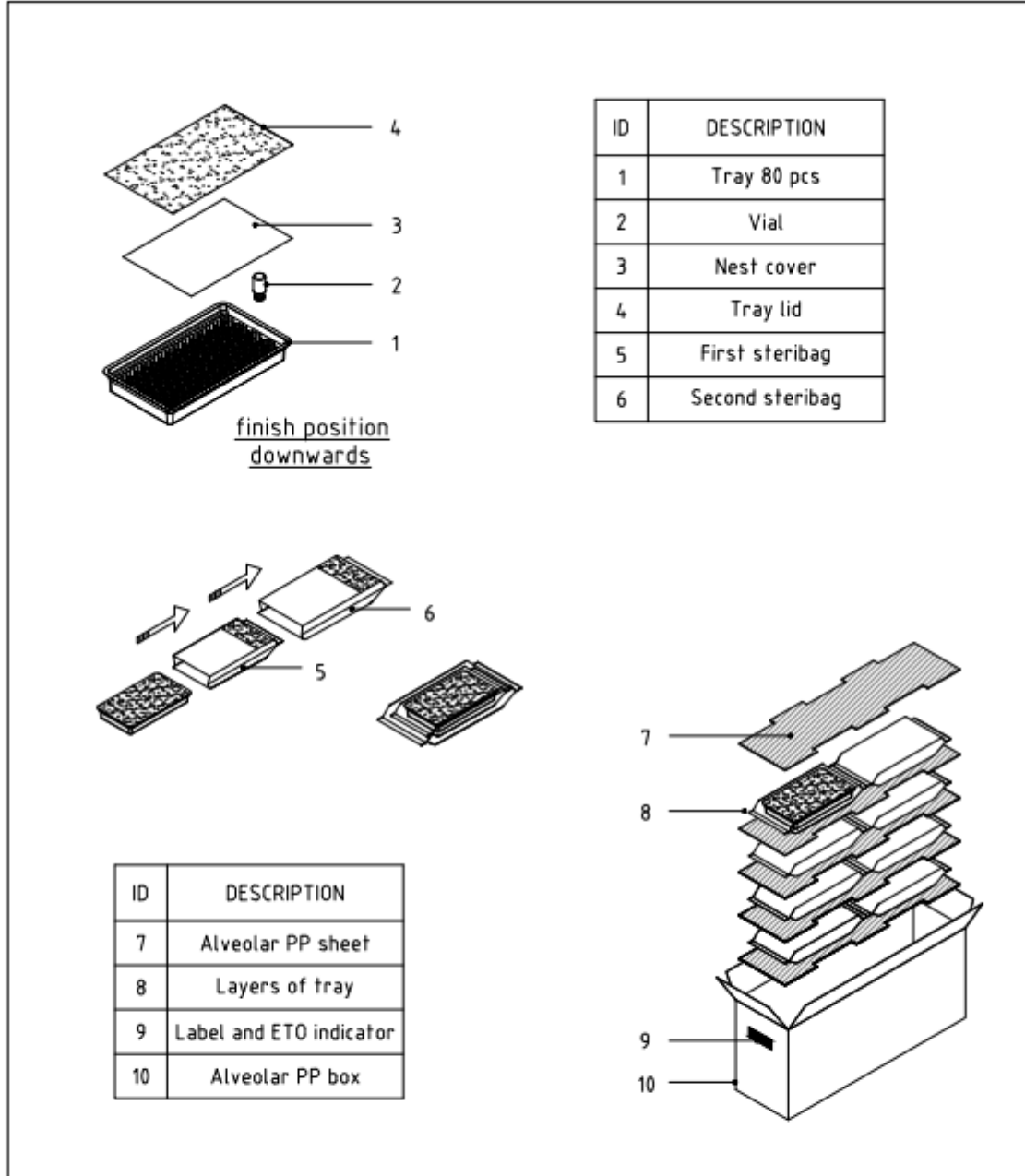
Material	Wood
Dimension	800 x 1200 x h1880 mm
Net weight	336 kg
Gross weight	460 kg
Layers per pallet	5
Boxes per pallet	25
Vials per pallet	16000


APPENDIX 1: VIALS DRAWING



Rev.	Notes	Signature	Dates	Dimensions without tolerances ISO 2768		
01	Updated with new SGD drawing revision	Made by GCO Approv. by FLI	29/07/2022 10:10 02/08/2022 11:29	Tolerances basing on ISO 8015		
00	First edition	Made by MRG Approv. by PTN	10/02/2022 11:55 10/02/2022 12:15	Format A4	Unit mm	Scale -
		Material:		Ex	Lang.	EN
Description		MOLDED VIAL 10H		Code 9778	Version A	Rev. 01
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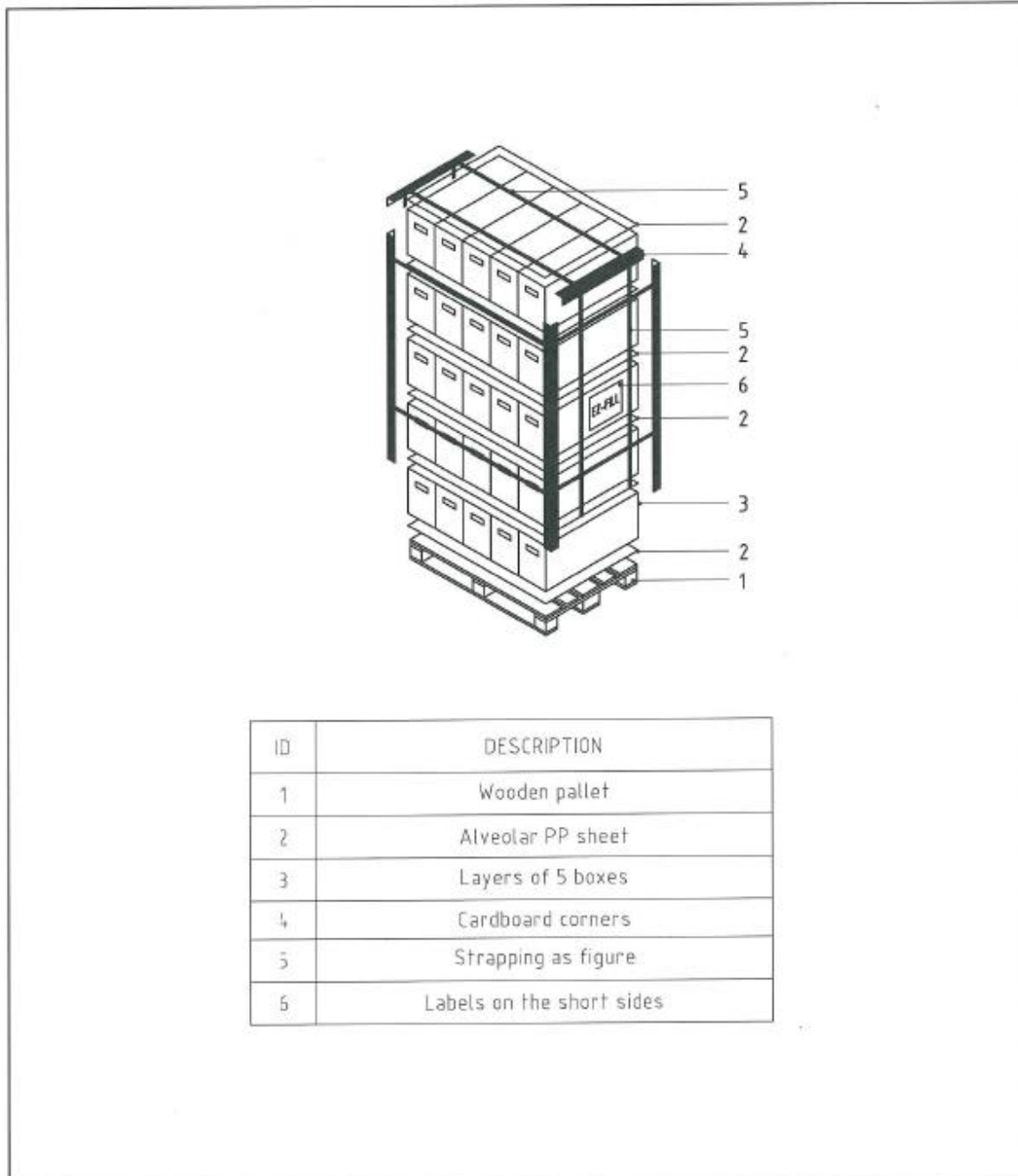
APPENDIX 2: SECONDARY PACKAGING SCHEME




Rev.	Notes	Signature	Dates	Dimensions without tolerances ISO 2768-vK					
00	First edition	Made by	GCO	27/05/2022 13:39	Tolerances basing on ISO 8015				
		Approv. by	PTN	27/05/2022 13:53	Format	Unit		Scale	
		Made by			A4	mm		1:20	
		Approv. by			Ex	Lang.	EN		
		Material: Description PRIMARY PACKAGING SCHEME			Code	Version	Rev.		
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									MOD 01L-07

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ID	DESCRIPTION
1	Wooden pallet
2	Alveolar PP sheet
3	Layers of 5 boxes
4	Cardboard corners
5	Strapping as figure
6	Labels on the short sides

Rev.	Notes	Signature	Dates	Dimensions without tolerances ISO 2768				
				Tolerances basing on ISO 8015				
01	New drawing template	Made by	MRG	11/04/2018 12:06	Format	Unit	Scale	
		Approv. by	AFE	11/04/2018 12:29				
00	First edition	Made by	PTN	09/06/2016 11:24	A4	mm	1:4.0	
		Approv. by	AFE	09/06/2016 12:07				
		Material:		Ex	Lang.		EN	
		Description		Code	Version	Rev.		
		SECONDARY PACKAGING SCHEME		PA04100	A	01		
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PALLET LABEL

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CUSTOMER:		CUSTOMER PO NUMBER:		FORM_CONT_EN_0079 FORM_CONT_EN_0080 FORM_CONT_EN_0078
CUSTOMER ITEM CODE:				
DELIVERY ADDRESS:		ESTIMATED GROSS WEIGHT (Kg):	BATCH NUMBER: PALLET NUMBER:	
DESCRIPTION:		BATCH NUMBER + PALLET NUMBER		
ITEM CODE:	QUANTITY PER BOX (PCS):	BOXES PER PALLET (PCS):	QUANTITY PER PALLET (PCS):	FORM_CONT_EN_0079 FORM_CONT_EN_0080 FORM_CONT_EN_0078
BATCH NUMBER:		PALLET NUMBER:	BATCH NUMBER + PALLET NUMBER	

MADE IN ITALY

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ADHESIVE BOX LABEL

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		Nuova Ompi S.r.l. Piombino Dese - ITALY	
DESCRIPTION:			
ITEM CODE:			
BATCH No.:			
QTY:			
DATE:	LABEL No.:		

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STERILIZATION INDICATOR

Rev.	Notes	Signature	Dates	Dimensions without tolerances ISO -				
06	CC-21-00139: Sterilizer removed	Made by: PTN	19/10/2021 08:49	Tolerances basing on ISO 8015				
05	Customer P.O. number added	Approved by: MMI	02/08/2018 16:57	Format	Unit		Scale	
				A4	mm		1:2	
		Material: -		Ex	Lang.	EN		
		Description		Code	Version	Rev.		
		LABEL AND ID LABEL		LB00115	A	06		
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