PRODUCT SPECIFICATION

Art. No.	**93900**
NAME OF PRODUCT	Dressing kits
DESCRIPTION OF PRODUCT	Dressing kits , EO pack
	Material: spunlace/plastic/PE film/tissue
	Valid for effectivity : once package opened
	Shelf life : 5 years
	Remark: Specifications pls. refer to attachments I, II
Classification (MDD, Annex IX)	Class Is Rule 4
INTENDED USE OF PRODUCT	For wound treatment

APPLICABLE HARMONIZED STANDARD

Standard No.	File Title
MDD 93/42/EEC amended byDirective 2007/47/EC	Medical Device Directive: Council Directive 93/42 EEC of 14 June 1993 concerning medical devices
EN ISO 13485:2016	Medical devices-Quality management systems-Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices-Application of risk management to medical devices
EN ISO 15223-1:2016	Medical devices-Symbols to be used with medical device labels,labeling and information to be supplied
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 10993-5: 2009	Biological evaluation of medical devices-Part 5: Test for cytotoxicity
EN ISO 10993-10: 2013	Biological evaluation of the medical devices-Part 10: Tests for irritation and skin sensitization
ISO 11135:2014	Sterilization of health-care products-Ethylene oxide-Requirements for the development, validation and routine control of a sterilization process for medical device
EN ISO14937:2010	Sterilization of health care products-General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
EN ISO11607-1:2009+A1:2014	Package of Terminal Sterilization Devices --- Part 1, Request of Material, Sterilization Inter layer and package system
EN ISO11607-2:2006+A1:2014	Package of Terminal Sterilization Devices --- Part 2, Authentication Request of Composition, Sealing and Assembling process
EN ISO 11737-1: 2006	Sterilization of medical devices-Microbiological methods-Part 1: Determination of a population of microorganisms on products
MEDDEV 2.4/1REV.9:2010	Guidelines relating to the application of the council directive 93/42/EEC on medical device
MEDDEV 2.7.1 Rev4:2016	CLINICAL EVALUATION:A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC

RAW MATERIAL

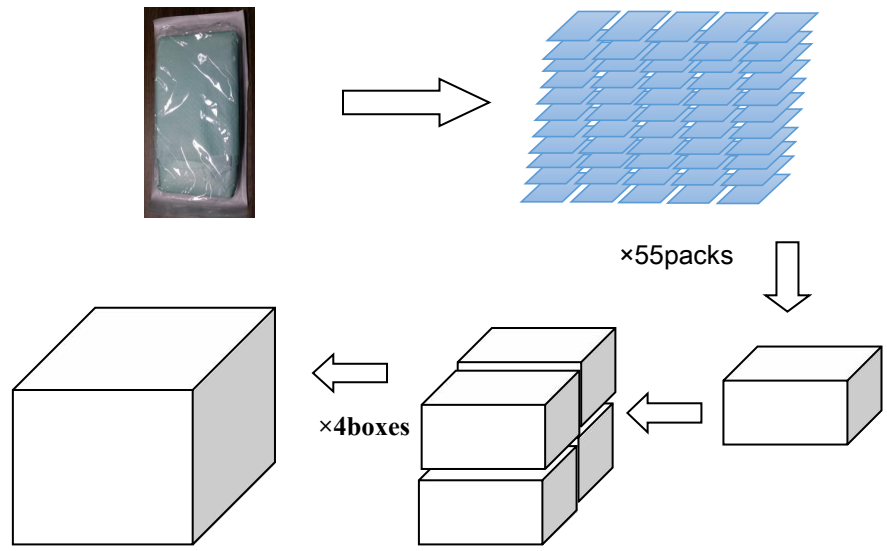
CODE FOR THE ENCLOSED	RAW MATERIAL	ADDITIONAL INFORMATION
RAW MATERIAL SPECIFICATION	Non-woven balls	Spunlace ,white
		Elastic ring, latex free
	Tray	PS, white
	Forceps	PS, light green
	Wrapping sheet	Tissue with PE film
	EO pouch	Tissue with PE film
	Closure tape	PP transparent tape
	Inner box	Paperboard, colours printing
	Transport carton	Double Wall Corrugated Fibreboard , white Weight: 650g/m^2

QUALITY SPECIFICATION OF THE PRODUCT

CHARACTERISTIC	TARGET VALUE	QUALITY TOLERANCES	TEST METHOD
FINISHED SIZE	Forceps= 128mm	+/- 1mm	Measuring
	Tray= 150×70mm	+/- 2mm	Measuring
	Wrapping sheet= 40×40cm	+/- 1cm	Measuring

DESCRIPTION OF THE PACKAGING SYSTEM

PACKING		
55sets/box, 220sets/ctn		
INNER BOX SIZE (cm)		
L	W	H
42	18	20
CARTON SIZE STYLE (cm)		
44	38	41.5



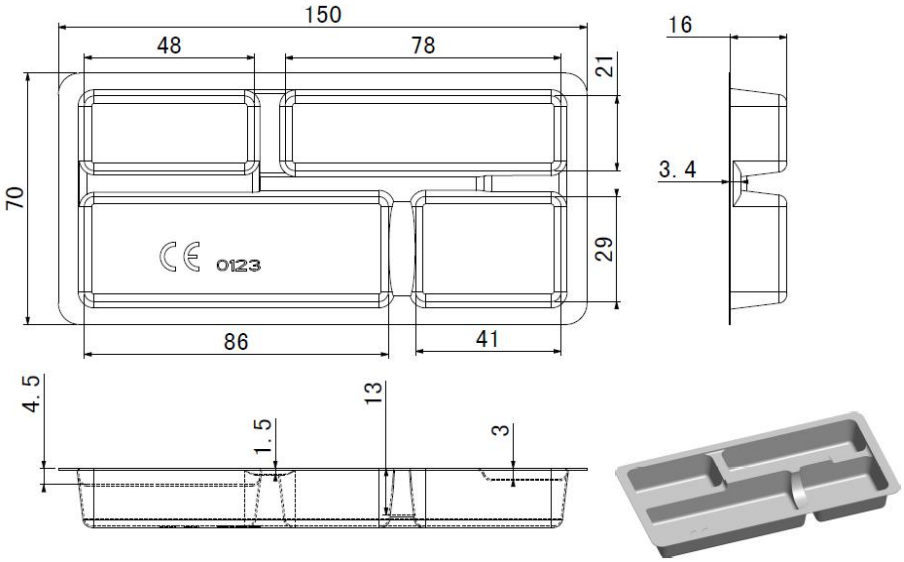
Dressing kits **Attachment I**

inside view

outside view

Tray drawing

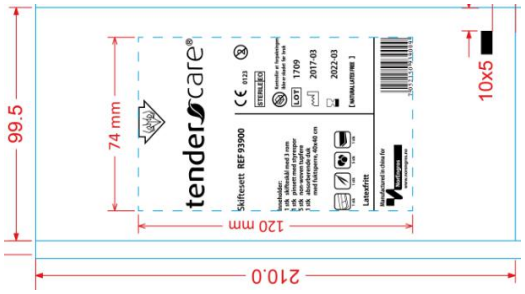
Attachment II



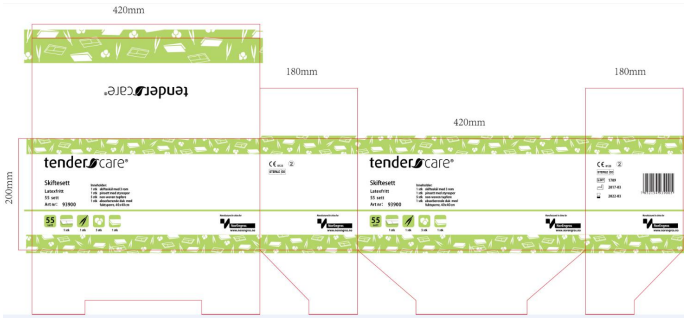
Printing/Label

Attachment III

EO pouch printing



Inner box printing



Carton printing