Technical Data Sheet

Soft-Zellin®

MEDICAL DEVICE

General Product Description/Intended Purpose

Soft-Zellin® is an alcohol swab made of nonwoven fabric, impregnated with isopropyl alcohol (70% v/v) ready to use for intact skin surface and is Non-invasive.
Intended user: For use by healthcare professionals and lay-user
Medical device class : I non-sterile ,based on Rule 1 of Annex VIII of the Regulation (EU) 2017/745.

Application/Indication

Soft-Zellin® is intended for skin cleaning prior to subcutaneous injections and the taking of capillary blood samples.
Isopropyl alcohol has cleaning properties by wiping over the skin it cleanses the skin in this area.
Applicable site: Unbreached skin
Open the primary paper bag packaging, take the Alcohol Pad out, use it to wipe intact skin surface for cleaning.
If the Alcohol Pads become dry out or dirty change to a new one.
When using Alcohol pad it must be ensured that the applied alcohol has evaporated completely before continuing.

Catalogue Numbers

Ref	Name	Size (mm)	Pieces per pouch	Pouch per Folding Box	Folding Boxes per transport carton
4110020	Alcohol Pads	60x30	1	100	70

Residual Risks, Contra-Indications and Undesirable Side Effects, Warnings

The use of Alcohol pad does not replace disinfection. If the injection point is very dirty, it should first be washed thoroughly with soap and water.
Avoid eye contact.
Keep out of reach of children.
Check the primary foil bag before using, do not use product if bag is opened or damaged.

Single Use Device

Reusing a single-use medical device is dangerous. Reprocessing devices, in order to reuse them, may seriously damage their integrity and their performance. Information available on request.

Product Disposal

To minimize the risk of potential infection hazards, or environmental pollution, disposable components of Soft-Zellin® should follow disposal procedures according to applicable and local laws, rules, regulations and infection prevention standards.

Incident Reporting

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

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Material Characteristics

Material	45(±3)g/m^2 non-woven, 50% Rayon + 50% polyester
Size of swab	30 x 60 (±2) mm, impregnated with 70% isopropyl alcohol, and then folded one time into a size of 30 x 30 (±2) mm.
Primary packing	Aluminum compound foil pouch

Labelling

Lot-No. with 9-Digit Code e.g.:

LOT	9	999	01	XX	1
explanation	[9 = 2019]	[000-999]			
definition	year	serial production order		for internal purposes only	

Date of Manufacture

e.g.	2015	04	01
	year	month	day

Use-by-Date

e.g.	2020	04	01
	year	month	day

Legal Manufacture:

Kingstar Medical (Xianning) Co.,Ltd.No. 79 Yong'andong Road, Xian'an District 437100 Xianning City, Hubei Province, the People's Republic of China

CH-REP

QS Engineering AG, Erlenstrasse 31 CH-4106, Therwil, Switzerland

EC-REP

Shanghai International Holding Corp. GmbH (Europe)Eiffestraße 80 20537 HAMBURG, GERMANY

Distributior/Importer

PAUL HARTMANN AG, Paul-Hartmann-Straße 12, 89522 HEIDENHEIM, GERMANY
IVF HARTMANN AG, Victor-von-Bruns-Strasse 28, 8212 Neuhausen, Switzerland

Shelf Life: 5 years

Medical Device MD

Unique Device Identifier (UDI) UDI

Inflammable

Latest Date of Revision: 2022-10-12