



Certificate

The SQS herewith attests that the organisation named below has a management system that meets the requirements of the normative basis mentioned.



CurTec International
Spoorlaan Noord 92
5121 WX Rijen
The Netherlands

Scope

Development, manufacture and sales of blow moulded and injection moulded plastic packaging products and products according to client's specification for the pharmaceutical industry

Normative basis


ISO 15378:2017

Primary Packaging Materials for Medicinal Products

Particular requirements for the application of ISO 9001:2015, with reference to Good Manufacturing Practice (GMP)

Reg. no. H42979
Page 1 of 2

Validity 07.10.2022–06.10.2025
Issue 15.05.2023


A. Grisard, President SQS


F. Müller, CEO SQS



Swiss Association for Quality and Management Systems (SQS)
Bernstrasse 103, 3052 Zollikofen, Switzerland





Appendix

Appendix of main certificate H42979



CurTec International
Spoorlaan Noord 92
5121 WX Rijen
The Netherlands

Central Function	Scope	Norm / Revision	Reg. no.	Validity
CurTec International Spoorlaan Noord 92 5121 WX Rijen The Netherlands	Development, manufacture and sales of blow moulded and injection moulded plastic packaging products and products according to client's specification for the pharmaceutical industry	ISO 15378:2017	H42979	07.10.2022 06.10.2025
Locations	Scope	Norm / Revision	Reg. no.	Validity
CurTec USA Oconee Industrial & Technology Park Oconee County Westminster, SC 29693 United States of America	Manufacture and sales of blow moulded and injection moulded plastic packaging products and products according to client's specification for the pharmaceutical industry	ISO 15378:2017	S81104	15.05.2023 06.10.2025

Reg. no. H42979
Page 2 of 2

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Certificado de Composição do Kit de Primeiros Socorros Conforme Exigências SOLAS

Os kits são compostos conforme exigências do MCA/Reino Unido, países de língua inglesa, comunidade Européia – EC/MED Wheel Mark – SOLAS/LCA Code.

Type approved Cat-C First Aid Kit provides the necessary medical equipment and stores required under the UK Ships Medical Stores MSN 1768(M+F) for all commercial vessels, charter boats, charter yachts, lifeboats and liferafts classed as operating under Category-C as defined by the EC Council Directive 92/29/EEC.

This Category-C First Aid Kit also fulfils both the Merchant Shipping & Fishing Vessels (Medical Stores) Regulations 1995 (SI 1995/1802) and the Merchant Shipping & Fishing Vessels (Medical Stores) (Amendment) Regulations 1996 (SI 1996/2821) for all vessels, lifeboats and liferafts classed as operating under Category-C as defined by the EC Council Directive 92/29/EEC and also under the SOLAS Life Saving Appliances Code (LSA).

This medical kit is supplied in a re-sealable waterproof foil bag.

Contents:

- Triangular Bandage x 04
- Wound Dressings Medium x 02
- Wound Dressings Large x 02
- Wound Dressings Extra x 02
- Elastic Bandage x 01
- Paraffin Gauze Dressings x 10
- Burn Dressing x 01
- Absorbant Cotton Gauze x 01
- Antiseptic Wopes x 06
- Antiseptic Cream x 01
- Adhesive Plasters x 20
- Analgesic Tablets x 50
- Diarrhea Tablets x 30
- Sea-sickness Tablets x 60
- Angina Preparation x 50
- Ibuprofen Tablets x 50
- Scissors x 01
- Disposable Gloves x 05
- Rustless Safety Pins x 06
- Resuscitation Mask x 01
- Aluminum Foil Wrap x 01
- English Instructions Paper x 01

Inmark Inc.
675 Hartman Road Suite 100
30168 Austell
United States of America

Rijen, February 27, 2013

Re : Certificate of conformity
Subject : Heavy metals and dangerous goods materials

It is herewith stated that the goods covered by this document are of Dutch origin and were manufactured in our plant in The Netherlands according to our ISO 9001, ISO 14001 and HACCP system checked by Lloyds Register Quality Assurance. The products comply with our Drug Master file number 16388 filed by the FDA in the USA and have UN certification.

The used raw materials and masterbatches are excellently suitable for foodstuffs checked by migration tests and do not contain any harmful components, such as Heavy Metals, Phthalates, Genetically Modified Organism (GMO), TSE (Encéphalopathies Spongiformes Transmissibles), BSE (Encéphalopathie Spongiforme Bovine), Bisphenol A (BPA), Dimethylfumaraat (DMF), Melamine or Substance of Very High Concern (SVHC).

We produce our products according directive 2002/70/EC which indicates that they are produced according to GMP for plastics.

We have preformed Moist Vapour Transmission tests and light transmission tests. The tests indicate that we comply with the USP <661> Plastic containers. Due to the fact that we only use food grade materials and previous tests indicates that we comply to the following regulations: EurPh 3.1.2 Polyolefin's and EurPh 3.2.2 Plastic containers.

Our reference : 7000 series white/red and/or UV protected, 6900 series white/red; brown beige and/or UV protected

Yours sincerely,



H.J. Pronk
QESH-Manager ai
CurTec Nederland B.V.