ONDAPLAST
SHAPE, STRENGTH AND LIFE

Ondaplast®

Pharmaceutical Packaging Products

Process and Manufacturing Management

Date of revision: 2020-09-16

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Table of Contents

ONDAPLAST
SHAPE, STRENGTH AND LIFE

1. Introduction

Ondaplast S.p.a. is one of the leading European manufacturers for corrugated plastics. Among other market segments, we are supplying also packaging products for the pharmaceutical packaging market.
Our industrial operations are aligned with the state-of-the-art standards.

This booklet has the aim to introduce the our procedures specially designed to meet the highest requirements and standards for the manufacturing of pharma packaging materials.


Main plant in Longiano, Italy

2. Ondaplast

Ondaplast S.p.a. was founded in 1982 in Longiano, Italy. The company has enjoyed a steady growth over the years. Present main data are:

- About 120 employees
- Production area 30,000 sqm
- Annual processed material: above 20,000 tons

Ondaplast Italy has a subsidiary in Serbia, Ondaplast Balkan.

Founded in 2018 in Subotica, Serbia, the Balkan operation of Ondaplast has today:

- About 40 employees
- Production area 10,000 sqm
- Annual extruded volume above 10,000 tons with two extrusion lines

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3. Manufacturing Procedures and In-Process Control

2.1 Operating process regarding cleanliness

Cleanliness and contamination prevention of the overall production areas where pharmaceutical components are processed are the key point of any success for both Ondaplast production plants.
The manufacturing areas for pharmaceutical applications are separated from standard areas. All provisions are taken to prevent the products from contamination with dust, hairs, liquids, foreign bodies or insects.
Palettes are clean and dry without any dust or broken parts.
Extrusion and converting equipment is clean and controlled on regular basis to minimise all sorts risks of contamination.
Converting environment is equipped with insects catchers.
Operation controls: the extrusion operators are responsible for the absence of any kind of contamination (grease, hair, liquids, wood particles, insects etc) before the palette is moved to the converting area. The converting operators are asked to control the reached materials before starting their operations.
Pharma packaging components are usually packed in parcels of 25 or 50 pieces each.

2.2 Semi-finished sheet materials

The semi-finished sheets are produced by extrusion process using raw materials only such as Polypropylene-copolymer and Polypropylene-homopolymer in different ratios depending on the final usage and customer specification (MFI range 1-2 at 230 °C, 2.16 kg).

The max. width (across the flutes) of Ondaplast® sheets is 2,800 mm.

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3.3 Contamination protection against human influence

In addition to the mandatory safety equipment all operators and persons that might get into contact with materials for pharmaceutical applications wear clean working clothes, white gloves, hair net or baggy cap and beard net if necessary.
Smoking, eating or drinking is strictly not permitted in whole Ondaplast production areas.
It is the responsibility of every Ondaplast employee to guarantee the absolute absence of every sort of contamination.

Assembly of partition grids for vial boxes
(dedicated pharma room).

2.4 Contamination protection for internal transportation

In order to guarantee the maximum of protection the palettes with semi-finished pharma parts get wrapped before internal transportation from extrusion area to converting areas in a similar way than for shipment.

Sample of transfer palette

Packing and visual contamination checks are done by the responsible extrusion workers on regular base in accordance with ISO 9001 rules.

- The bags (or films) are used one time each and never re-used.
- Palettes are dry, clean and without any broken part or chips.

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2.5 Die-cutting process

For stress reduction within the extruded semi-finished sheets a dwell time of not less than 36 hours is kept before the die-cutting is executed.

Die cutting tools are generally produced by a very limited number of proven subcontractors according to Ondaplast S.p.a. drawings and specifications.

In order to ensure that the tool used is in relation with the latest design approved by the customer, this operating tool is controlled using the working procedure described in the Quality Manual (ISO 9001 QM handbook).

The wide range of Ondaplast S.p.a. die cutting machines offers the possibility to reach the best results (e.g.: size precision, absence of undesired deformations) for every sort of pharma component and independently by its size.

- 3 high speed Bobst machines (5,000 pcs/hour output and size up to 1,200x2,000 mm).
- 3 large size machines (width up to 2,400 mm)
- Various “platina” die cutting machines
- 1 CN machine with table size 3,200x2,200 mm

Loading of a Bobst machine with sheets

2.6 Additional steps

After die cutting operations some additional steps might be necessary for some pharma packaging components. These operations could be welding, printings, removal of cut outs.
For cut out removal Ondaplast S.p.a. has developed a unique two table machine operating in combination with an industrial robot. The machine lay-out with double working table totally cancels the dead times of the machine.

Check before final packing

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3.0 Quality Control

3.1 Testing of corrugated PP-sheets

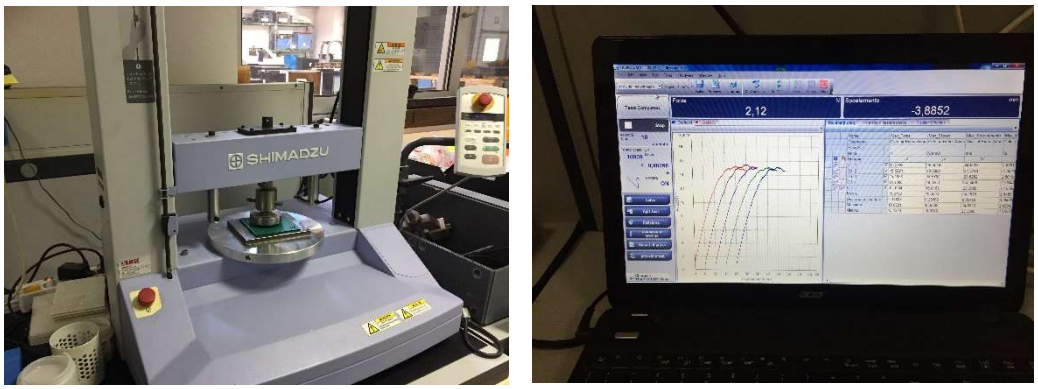
The quality of extruded polypropylene products is defined and controlled by 3 parameters:

- Thickness [mm]
- Grammage [g/m²]
- Compression resistance [N/mm²]

Quality control of above mentioned parameters is done by use of the following measuring equipment:

- Thickness: micrometre caliper
- Weight: scale
- Compression resistance: compression press

Mechanical properties of Ondaplast® PP-sheets				
Property		Method	Value	Unit
Maximum compression stroke	2.0 mm / 350 gr	internal	>25.0	[N/cm^2]
	2.0 mm / 400 gr	internal	>35.0	[N/cm^2]
	3.0 mm / 650 gr	internal	>55.0	[N/cm^2]



Compression test: equipment and graphs

3.2 Self-Control applied by workers.

According to ISO 9001 Ondaplast S.p.a. put in place a Self-Control system for workers involved in Pharma components manufacturing. These employers tick appropriate production documents taking track of relevant production parameters and steps and ensuring they are compliant with the rules fixed in Quality Handbook.

3.3 Laboratory control

Samples are taken on a regular basis from standard production and tested in a dedicated laboratory to guarantee compliance of product features with specifications.

3.4 Hygienic control

Depending on UNI EN 15593 requirements chemical and microbiological reviews are done on finished products to monitor the hygienic level and to guarantee the quality of Ondaplast® materials.

3.5 Master batches

Master batches are available upon request.

4.0 Packaging

4.1 Primary Packaging

After die-cutting the sheets get bundled in small and easy-to-handle packs of usually 25 or 50 sheets. These packs get overall wrapped with wrapping film as a first protection.


Bundle of sheets in front of wrapping machine


Wrapped bundles before stacking on palettes

4.2 Shipment packaging

Palette ready for shipment

Corner protections are placed on customer request over the whole length and width of the sheets to avoid any damage.

6. Traceability and Product Identification

Each palette is identified by a unique label from extrusion to shipment.

At reception of customer's order, a production order (internal order) is issued.
This document and the related manufacturing labels are unique and gather all information regarding this particular order:

- customer reference
- production code
- product references
- weight/m²
- colour
- quantity
- final delivery packaging

The label mentioned above collects all information related to the manufacturing process and allows to track at any time the history of manufacturing parameters like

- raw materials used
- extrusion line
- die cut machine
- production shift
- operators involved
- converting tools used

This label includes check boxes where operators sign that all controls have been done in accordance with process specifications.

All manufacturing informations are kept available for a minimum of 5 years.

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6.0 Annex 1: Certificates

CERTIFICATE

TÜV AUSTRIA

Management system as per
EN ISO 9001:2015

In accordance with TÜV AUSTRIA CERT procedures, it is hereby certified that

ONDAPLAST

Ondaplast spa
Via Crocetta, 3310
IT-47020 Longiano (FC)

applies a management system in line with the above standard for the following scope

Design and manufacture of plates and packaging made of thermoplastic material.

Certificate Registration No. 20100131340060

Valid until: 2021-11-20
Initial certification: 1997-04-28

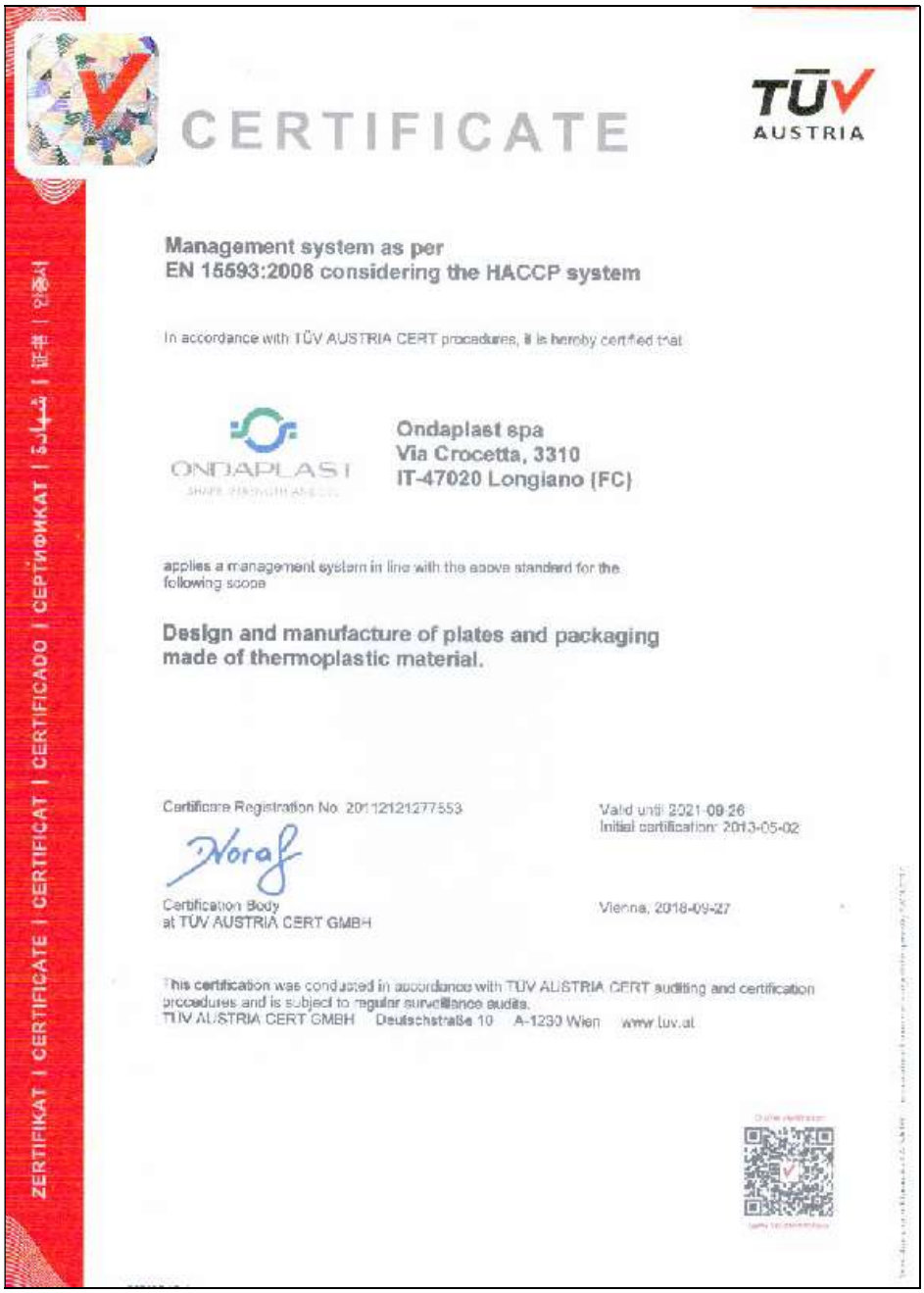
Certification Body
at TÜV AUSTRIA CERT GMBH

Vienna, 2018-09-27

This certification was conducted in accordance with TÜV AUSTRIA CERT auditing and certification procedures and is subject to regular surveillance audits.
TÜV AUSTRIA CERT GMBH Deutschstraße 10 A-1230 Wien www.tuv.at

ZERTIFIKAT | CERTIFICATE | CERTIFICAT | CERTIFICADO | СЕРТИФИКАТ | شهادة | 证书 | 인증서

ISO 9001 cerificate



CERTIFICATE

TÜV AUSTRIA

ZERTIFIKAT | CERTIFICATE | CERTIFICAT | CERTIFICADO | СЕРТИФИКАТ | شهادة | 证书

Management system as per
EN 15593:2008 considering the HACCP system

In accordance with TÜV AUSTRIA CERT procedures, it is hereby certified that

ONDAPLAST

Ondaplast spa
Via Crocetta, 3310
IT-47020 Longiano (FC)

applies a management system in line with the above standard for the following scope

Design and manufacture of plates and packaging made of thermoplastic material.

Certificate Registration No. 20112121277553

Valid until 2021-09-26
Initial certification: 2013-05-02

Certification Body
at TÜV AUSTRIA CERT GMBH

Vienna, 2018-09-27

This certification was conducted in accordance with TÜV AUSTRIA CERT auditing and certification procedures and is subject to regular surveillance audits.
TÜV AUSTRIA CERT GMBH Deutschstraße 10 A-1230 Wien www.tuv.at

EN 15593 (HACCP) certificate

CERTIFICATO

kiwa

Reg. Numero ALI 01279 PM

Data di rilascio 2015-08-07 Data di ultima modifica 2018-08-07

Data di prossimo rinnovo 2021-08-07

Certificato di conformità
UNI EN 16636: 2015 Pest Management

Si dichiara che l'Organizzazione:

RADIS S.r.l.

è conforme alla norma:

UNI EN 16636:2015 "Servizi di gestione e controllo delle infestazioni (pest management) - Requisiti e competenze"

per i seguenti prodotti-servizi:

Erogazione del servizio di gestione e controllo infestazioni (pest management)

Chief Operating Officer
Giampiero Belcredi

Il mantenimento della certificazione è soggetto a sorveglianza annuale e subordinato al rispetto dei requisiti contrattuali di Kiwa Cermet Italia.
Il presente certificato è costituito da 1 pagina.

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

CERMET

RADIS S.r.l.
Sede Legale e Operativa
-Via Faentina 280 - 48124 San Michele RA - Italia

EN 16636 certificate

SIECO

Rapporto di prova n°: 0258

Revisione n°: 00
Data emissione: 15/06/2020
Pagina 1 di 1

Committente: **Ondaplast S.p.a.**
Via Crocetta, 3310
47020 Longiano (FC)

OGGETTO: ANALISI CHIMICA / MICROBIOLOGICA

LUOGO DI CAMPIONAMENTO: Via Crocetta, 3310 - 47020 Longiano (FC)

ESECUTORE DEL PRELIEVO: SIECO S.r.l.

TIPO CAMPIONE: Lastra alveolare per imballaggi PRIMARI.

DESCRIZIONE CAMPIONE: Lastra in USCITA magazzino per mercato FARMACEUTICO, lastra n. 4, commessa 228545, data produzione 07/05/2020, pedana 04/04, art. 38543, lotto 161800128204; committente: Nuova Ompi Srl.

DATA D. CAMPIONAMENTO: 07/05/2020

IDENTIFICATIVO DEL CAMPIONE: 052703L

PARAMETRO RICERCATO (Metodica Utilizzata)	Unità di Misura	Valore Misurato	Incertezza di misura	Valore Limite
Carica batterica mesofila totale (ISO18593 - Nordva Compact Dry n.039)	ufc/dmq	70	+3,50	1.000 (10.000)
Enterobatteriacee (ISO18593+AFNOR 3M)	ufc/dmq	< 10	-	100
Salmonella spp (ISO18593+E579)	ufc/dmq	assente	-	assente
Stafilococco Coagulasi Positivo (ISO 18593+6888-2)	ufc/dmq	< 10	-	100

Le Prove di analisi sono annullate a laboratori esterni certificati e convenzionati con SIECO S.r.l.
Valori limite ex linee guida Regionali per superfici sanificate (fra parentesi valori limite marginali per alimenti e.g.)

Il Responsabile del laboratorio

Dottore in Fisica Chimica Industriale 1357

SIECO S.r.l. Via Flaminia, 171 - 47923 Rimini - C.F./P.IVA: 02 507 070 418 - Tel./fax: 0541/786198 - Email: siecosr@gmail.com

Sample of test report: chemical / bacteriological analysis