

# ***ILHAPLAST***

*"Custom moulding specialists... to take you further"*





*Being recognized in the market as a manufacturer of high quality Plastic Pharma Primary Packaging products*



*To satisfy our customers' needs*



# ILHAPLAST Today



<p><b>50 +</b> <b>MILLION</b> Units / Annual Capacity</p> 	<p><b>&lt; 8</b> <b>WEEKS</b> Developing new Items</p> 	<p><b>4.000</b> SQM <b>INDOOR AREA</b></p> 
<p><b>100 +</b> <b>ITEM</b> <b>REFERENCES</b></p> 	<p><b>3 CLEAN ROOMS</b> ISO 7 / 8 - FDA 10.000 / 100.000 - EU GMP GRADE C / D</p> 	<p><b>&gt; 90%</b> <b>PHARMA IND.</b> Of Turnover %</p> 
<p><b>&gt; 90%</b> <b>EXPORT</b> Of Turnover %</p> 	<p><b>LEAN</b> <b>PRODUCTION</b> Ongoing Implementation</p> 	<p><b>SLA</b> <b>APPLIED</b> &amp; Controlled</p> 

# ILHAPLAST Customers



*" ... make us proud with their confidence"*



# ILHAPLAST Standards



NP EN ISO 9001:2015 / ISO 15378:2017



# **ILHAPLAST** DMF (Drug Master File)



**DMF Holder  
With the FDA  
(U.S. Food and Drug Administration)**

**Drug Master File Nr.º  
30228**



**Certificate of Drug Master File (DMF)**

**Service Period**  
June 1, 2021 – May 31, 2022

*This certifies that:*

**Ilhaplast, S.A.**  
**Lote 87, Zona Industrial de Vagos,**  
**Vagos, Aveiro 3840-385**  
**Portugal**

is a Drug Master File holder with the U.S. Food and Drug Administration pursuant to part 314 of Title 21, US Code of Federal Regulations, such filing having been verified as currently effective on the date hereof by Registrar Corp.

Drug Master File Number: **30228**  
Status: **Active**  
Type: **III**  
Subject: **PHARMACEUTICAL PRIMARY PACKAGING**

Registrar Corp will confirm that such filing remains effective upon request and presentation of this certificate until May 31, 2022, unless terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. Registrar Corp assumes no liability to any person or entity in connection with the foregoing. Filing of a Drug Master File does not in any way denote approval of the firm or its products by the U.S. Food and Drug Administration. Any representation that creates an impression of official approval because of filing of Drug Master File is misleading. The U.S. Food and Drug Administration does not issue a certificate of Drug Master Files. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.

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David Lennarz  
Executive Director  
Registrar Corp  
Dated: April 13, 2021

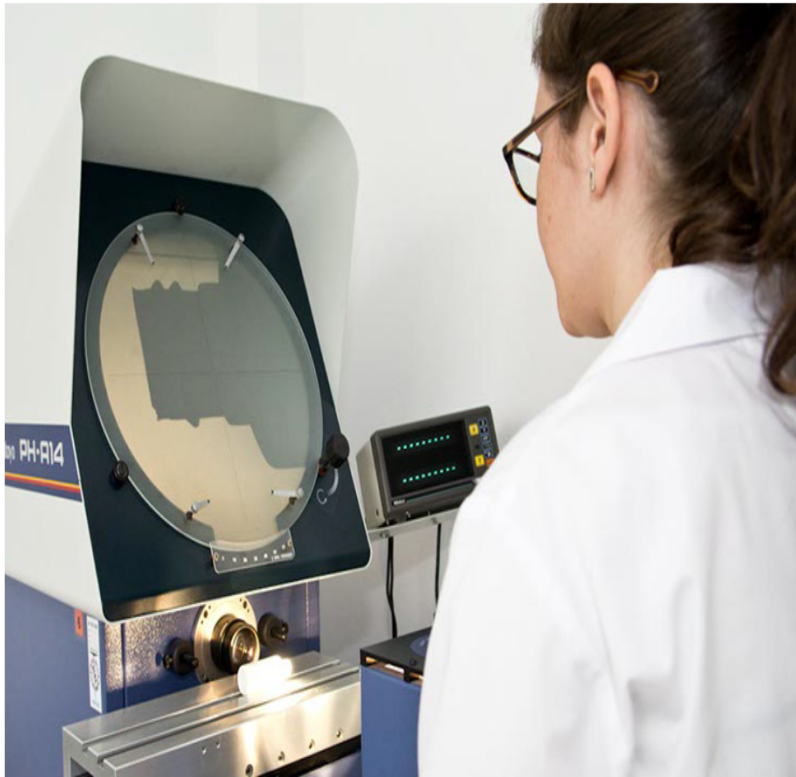
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# **ILHAPLAST** *Quality Policy*



*Focused on people, high productivity, effectiveness, efficiency and differentiation in products and services through continual improvement.*



# ***ILHAPLAST*** Production



***State of the art production facilities compliant with the international standards.***

***Production management following the Lean Manufacturing principles.***

***Quality checked at every production stage through systematic sampling and testing based on a very well documented and implemented quality assurance system.***



# **ILHAPLAST** Clean Rooms



**3 Clean Rooms ISO 7 / 8 classification - FDA 10.000 / 100.000 – EU GMP GRADE C / D.**





***At Ilhaplast 3 distinct manufacturing processes are implemented, for which we have modern equipment properly prepared to produce HDPE, PP and PET primary packaging and plastic parts in controlled environments and / or Clean Rooms (3 units);***

- Extrusion Blow Moulding (EBM). Equipment of different types and capacities, among which 4 "Magic" electric machines suitable for operating in Clean Rooms (one of them operates exclusively under these conditions).***
- Injection Blow Moulding (IBM) and (ISBM-PET). State-of-the-art equipment, such as Jomar 65 (with a clean room incorporated) to produce HDPE and PP plastic containers and Nissei ASB 12M, for the production of PET plastic bottles, which operates exclusively in a Clean Room.***
- Injection. Different machines with adequate capacity to produce HDPE and PP plastic parts, such as caps, measuring devices, etc.***

# ***ILHAPLAST*** Wrap Up



- 1. Flexibility in product development, offering best quality standard or customized items.***
- 2. Very convenient production batch sizes.***
- 3. Teams fully committed to meet our customer's satisfaction.***
- 4. 3 unique Clean Rooms compliant with ISO 7 and 8 - FDA 10.000 / 100.000 - EU GMP GRADE C / D, enables us to powerfully focus on Pharma Industry (currently representing approximately 90% of our turnover) .***
- 5. Raw Materials fully certified and compliant with USP and EP Standards.***
- 6. Consistent labelling and pallet tagging ensure seamless traceability of materials.***



A nighttime photograph of a Venetian canal. Several gondolas are moored along the left bank. The background features a row of historic buildings with many windows lit up, reflecting in the water. Palm trees are visible on the left side of the canal. The overall scene is illuminated by warm, yellow light from the buildings and streetlights.

***ILHAPLAST***

***"...we plan launching valuable new packaging solutions soon".***

***Thank you for your time!***