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Product case: Multiple technologies applied in one IVD-MD product (In Vitro Diagnostic Medical Device)

For our customer FABPulous BV, we produce their complete patented diagnostic test device - packed and ready for distribution to hospitals, general practitioners and to other medical specialists.

In the co-development and engineering phase, we could offer our customer the advantage of having so many technologies in house. Today, we are producing their device which is composed of two sub-assemblies: a plasma separation module and a lateral flow test module:

So what is involved in making these parts?

- 2K moulding of a liquid container as a hard-soft combination
- Accurate filling the container with a liquid
- Sealing it with multilayer seal
- Moulding and assembly of a plastic needle. When using the device this needle pierces through the seal to release the liquid
- Injection moulding of collector parts with external as well as internal screw thread
- Handling and placing of filter stacks in both the collection part as well as the test part
- Assembly of test strip, sealing and printing
- Full assembly and packaging is done in a cleanroom. Both sub-assemblies are individually packed in labelled pouches sealed and then, as a set, placed in their final packaging, ready to be send to the users.
- In addition to these technologies, Helvoet also manages the entire supply chain: raw materials, master batches, filter materials, test strip, liquid, seal, pouches, leaflet with "instructions for use", desiccant bags and boxes.

With this integral approach, we are able to fulfil our customer's need for an efficient and reliable contract manufacturer where all manufacturing technologies are combined under one roof.

On FABPulous and the patented FABPulous device:
The project was started by a grant from the EU H2020 program, with one of the purposes to transfer and concentrate the manufacturing and assembly of the H-FABP TRT prototype from various US-based development partners to one EU-based company, for which Helvoet Rubber & Plastic Technologies was selected. Benefits from this transfer are reduced parts cost-price by using newly manufactured serial moulds for injection moulding the parts. Additionally, supplier control is simplified by having only one partner for parts manufacturing as well as assembly of the parts into finished devices, including labelling and packaging, that is located nearby.
Throughout the project, Helvoet engineers provided the right technical and project support, pragmatism and perseverance for successful realization of the production tools and processes.

Interested in developing and/or manufacturing your functional product?
Contact our team and we are happy to help you.