MEDICAL DEVICE REGULATION

MATERIAL TESTING STRATEGY
BATCH INFORMATION

paromed®

NEW MEDICAL DEVICE REGULATION
Material testing strategy - Batch information

General information

As the new MDR will now come into force on May 26th, 2021, we want to seize this opportunity to inform you about the restructuring of our QM measures regarding our EVA materials.

Our renewed efforts could be described as "combining the necessary with the practical". By expanding our QM measures in a targeted manner, we fulfill the requirements of the MDR and, at the same time, gain new insights into how the profile of material properties could be optimised further in the future.

Making use of internal and external laboratory capacities, we will in the future not only test compliance with statutory requirements regarding prohibited additives, or the maximum permissible concentrations of certain additives and the cytotoxic properties of the compounds, but also the consistency of the composition of the processed materials and the resulting mechanical properties.

A dynamic material test is intended to supplement the limited informative value of a static Shore A value test, in order to allow us to provide more detailed information that can be used for the best individual design of orthopaedic insoles in the future.

Declaration of conformity for the blank material

As part of our new testing strategy, the EVA material undergoes cytotoxic testing as well as testing according to REACH, CADS and SG-PFI (already carried out in the past). Detailed information can be found on the declaration of conformity provided by us.

Chemical fingerprint

In addition, we have decided to carry out a continuous chemical analysis of the EVA material in order to be able to test the compounds used across the different batches for uniform composition.

The results represent a „fingerprint" of the material and enable us to identify the problem quickly and furthermore, know exactly where to look for the source of the problem, if tracing was necessary.

Three methods are applied to obtain the chemical fingerprint. We have contracted a DAKKS-accredited analytical laboratory to carry out the measurements on our behalf.
The methods applied are three complex analytical procedures:

- FTIR - Fourier-Transform Infrared Spectrometry
- DSC - Differential Scanning Calorimetry
- GPC - Gel Permeation Chromatography

You can find typical analysis patterns for our EVA materials according to these methods in **Appendix**.

In the event of any deviation, it will allow us to quickly locate the problem as well as understanding the possible implications.

This would make things come full circle in a double sense: on the one hand, with regard to increased material safety and, on the other hand, in the direction of sound future material development.

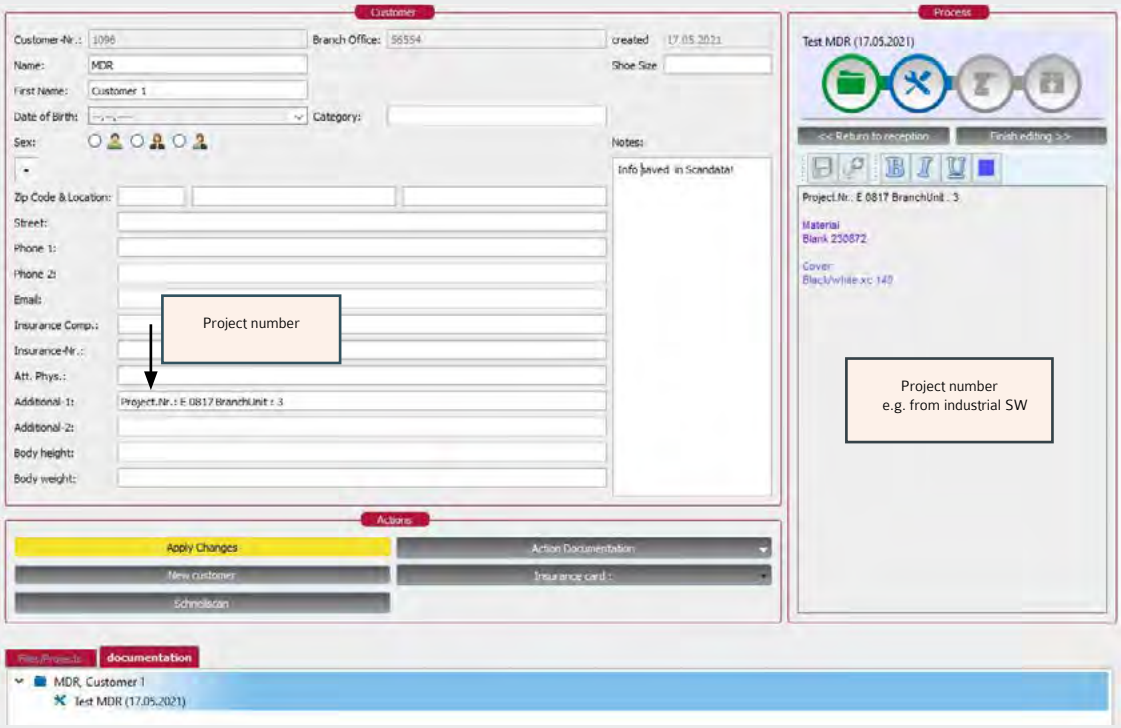
Batch information

Until further notice, the batch number on our blank boxes will constitute the batch information. Once we have gained clarity in the future, as to whether the majority of our customers works with barcodes or QR codes, we will supplement the batch number with a device-readable code for batch identification.

The batch numbers of the delivered blanks are also printed on the delivery note as a QR- and barcode. According to the new MDR, you are required to save this batch information under your insole project. Depending on your company's data processing strategy, you can process this data in your business software or under the individual process in the paroManager.

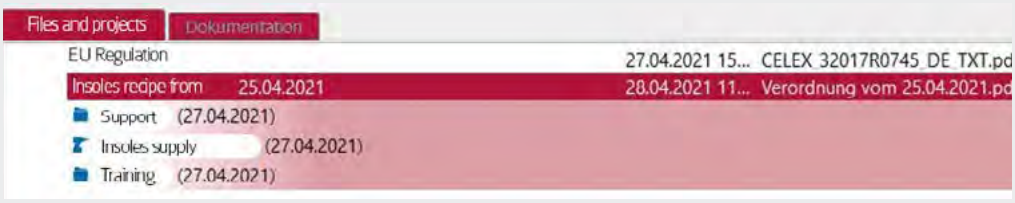
Under "process", (Customer -> Insole fitting -> Process), you create a unique project number, which you can use to store the batch number of our blanks as well as the batch numbers of the adhesive and cover material batches used in the documentation. You can store these numbers in the process documentation using an appropriate abbreviation.

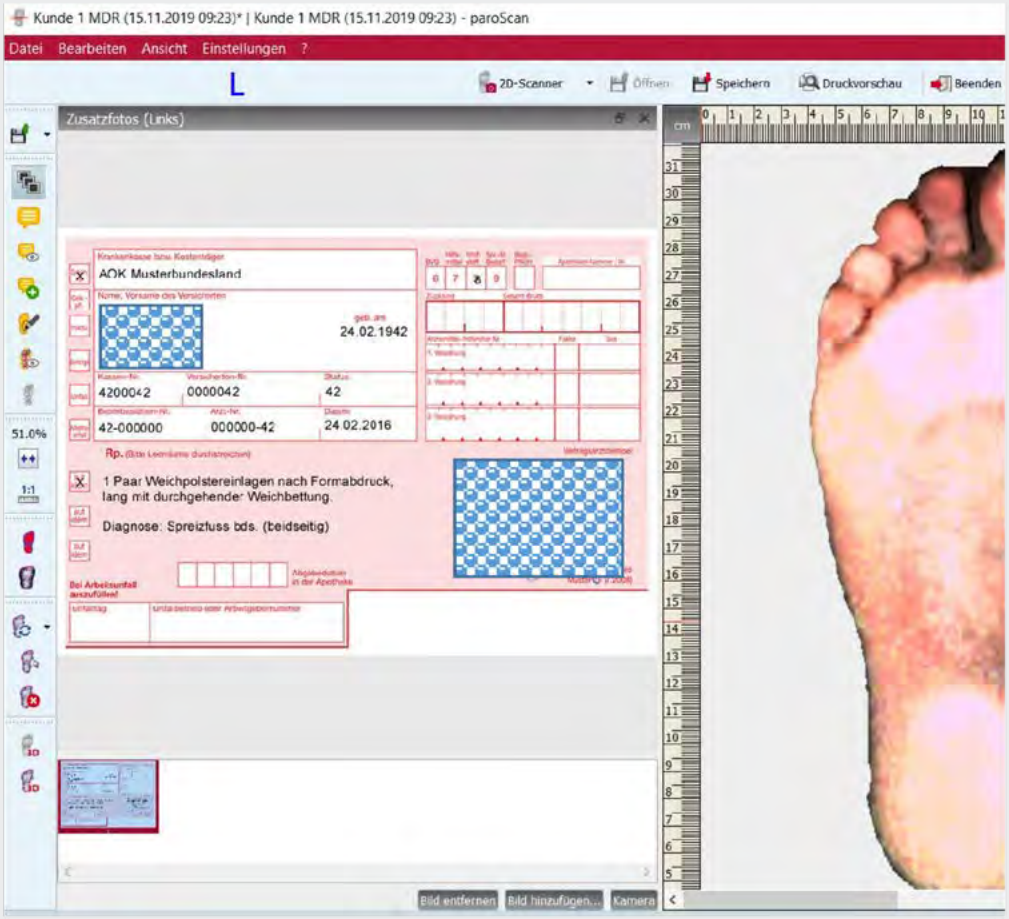
To print the project number on the insole label, the project number must be copied from the process note into the "Additional-1" field.



You can search and filter all process note entries in the database. This ensures that, in the event of a problem, you can also search for other customers who have been supplied with insoles made from materials of a problematic material batches, enabling you to initiate the recall in a targeted manner (keyword: post-market surveillance).

The prescription itself can either be assigned to the customer as a project file (e.g. in PDF format) or saved as an additional image directly in the scanning software:





Example: Prescription filed with the scan.

Additional information for paromed OrthoCAM customers

Since our central manufacturing is also subject to the requirements of the MDR, of course, we will provide the insoles with a unique identifier from the effective date. Depending on your wishes, we will transfer the required information onto the insole by laser or with an inkjet printer.

As you know, the MDR requires that individually manufactured devices must be labelled with the following information:

- Inscription "custom-made"
- Unique identifier (serial number, patient code or similar identifier)
- Statement that the product is a medical device
- Name of the manufacturer and
- Address of the manufacturer's registered office;
- Date until which the product is safe to use, alternatively indication of the date of manufacture (see at dgihv.org)

The delivery notes will be modified in such a way that the EVA batch is printed for each commission. If additional materials such as top covers are supplied through us, the batch numbers of these materials are also recorded and documented (also on the delivery note).

Alternative to label printers

Although special labelling of individual insole has been mandatory for a long time, this used to be somewhat difficult to achieve technically.

We are therefore pleased, to present our hand-held label printer that uses inkjet printing technology. It can easily be controlled via paro360 in the same way as conventional label printers.

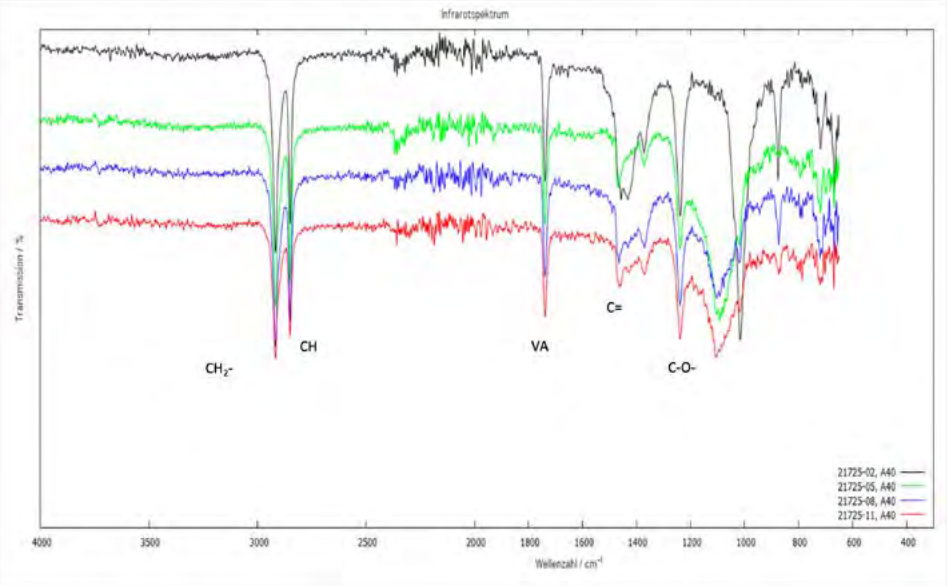
The printing colours can be adapted to the colours you have chosen for the material of the blanks. One ink cartridge can be used to label up to 2,000 pairs of insoles.

For more information, check out our short video at paromed.de/en/paroPrint.

Sample of a milled EVA insole printed with yellow and black labelling.

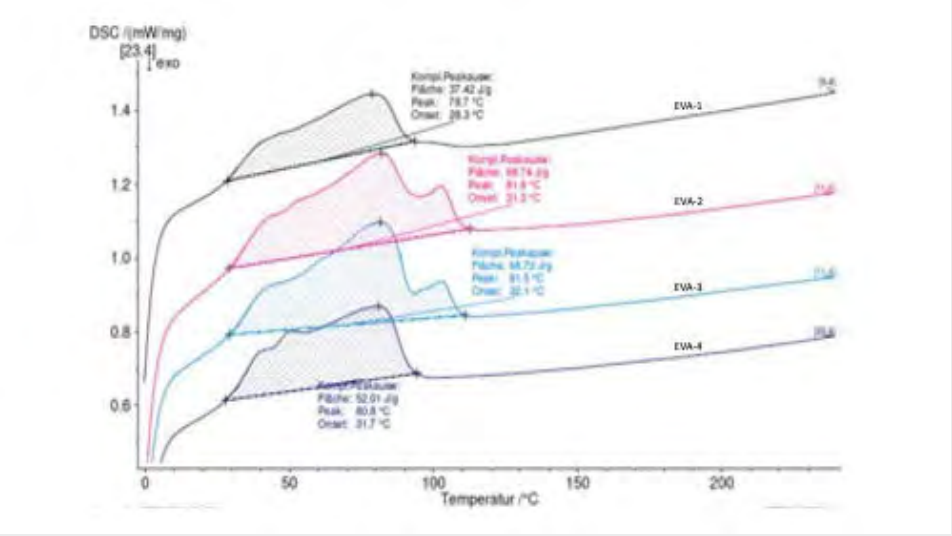
If you have any questions about any of the topics discussed, please do not hesitate to contact us at info@paromed.de.

A FTIR – Fourier-transform infrared spectrometry



IR spectroscopy is used for the determination of IR-active substances. They are identified by comparing the spectra or using reference spectra from a library. The irradiation of molecules with infrared light causes their bonds to vibrate. At the same time, this leads to energy absorptions of certain frequencies in the infrared spectrum, which can be used to identify the molecules.

B DSC – Differential scanning calorimetry

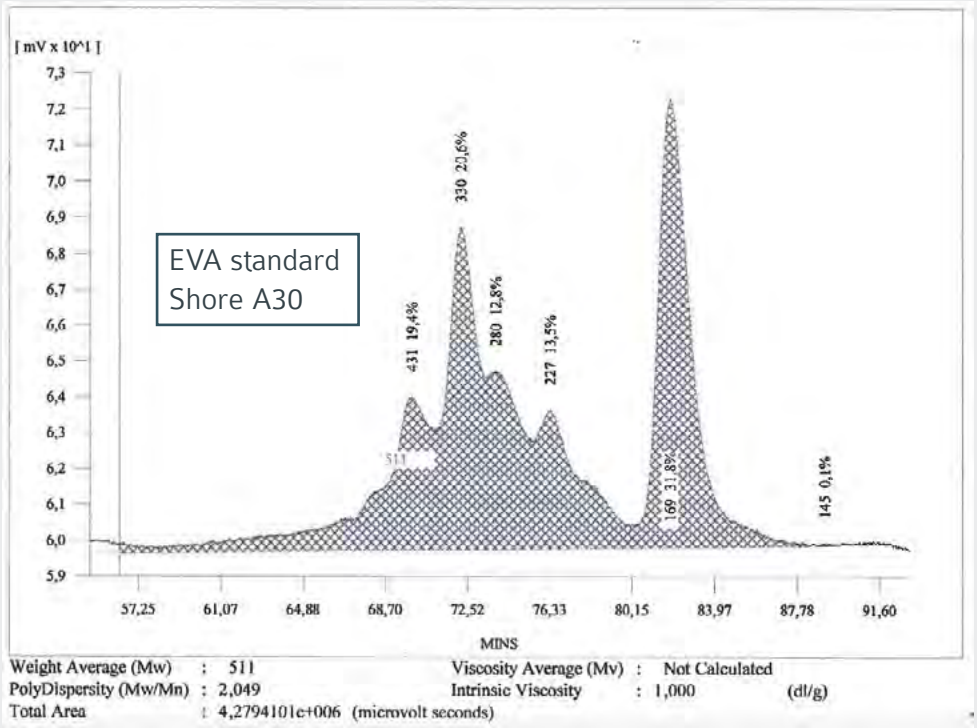


DSC is performed in accordance with DIN EN ISO 11357-1:2017 and DIN EN ISO 11357-3:2018. The difference in heat flow from the furnace (heating element) to the sample or from the furnace to the (chemically inert) reference sample is measured as a function of the temperature.

The measured signal, i.e. the area under a peak of the measurement curve, is directly proportional to the heat absorbed (endothermic process) or released (exothermic process). DSC is therefore a method for the quantitative measurement of heat effects (enthalpies) and their associated temperatures between the sample and the reference sample.

Two heating phases are completed for analysis of the plastics. The first heating phase allows conclusions to be drawn about the thermomechanical history (e.g. caused by processing) of a plastic. The second heating phase provides information about the substance-specific properties.zu.

C GC - Gel permeation chromatography



This method separates dissolved samples of the material to be analysed into to their constituents (using so-called separation columns). The separation columns have different porosities, resulting in different throughput times for the differently sized constituents of the material to be analysed. The individual phases of the sample then undergo molecular mass analysis, e.g. using UV detectors.

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