Serial and Lot Number Management of our Products and Outlook on the UDI Introduction

Dear Customer,

The Medical Device Regulation 2017/745 (MDR) already came into effect on 25 May 2017. However, the legislator has allocated a three-year transition period, which has been extended by one year due to the coronavirus pandemic. You, as a distributor of custom-made products, and we, as a manufacturer of Class I medical devices, must comply with the requirements of the Regulation by 26 May 2021. An important MDR requirement for manufacturers of medical devices is the obligation to issue serial and lot numbers.

A **serial number** is the unique designation of a product by the manufacturer. It is applied as an identifier for the elements of a series, and thus allows the production conditions and components used to be traced.

If a certain quantity of a product is manufactured or packaged under the same conditions, it is called a lot. Via the corresponding **lot number** it is possible to determine exactly which products comprise the lot and when it was produced and packaged.

The difference between a serial number and a lot number is that serial numbers are only used once to identify a product, while items with lot numbers, which refer to larger production quantities, can be used in different products.

As a manufacturer of medical devices, we use serial numbers, among others, for our system joints for the production of individual orthoses. We use lot numbers, among others, for our materials and therapeutic shoes.

Where Can You Find Our Serial and Lot Numbers?

The relevant numbers can be found on our delivery notes, invoices and credit notes as well as on the return forms and product packaging**.**

How Do You Use the Serial and Lot Numbers as a Manufacturer of Custom-Made Products?

You must record the relevant numbers in your patient file specific to the product.

Why is it Important for You to Keep the Serial or Lot Number for Our Products?

Without the documentation of the serial or lot number, the post-market surveillance of the medical device is not feasible. As the manufacturer, we are also incapable of implementing our product traceability system or process any returns without your documentation of the serial or lot number. Therefore, no credit note can be issued for the item sent to us.

With the introduction of product-specific serial and lot numbers from 26 May 2021 onwards, we will ensure the legally required transparency regarding the traceability of our products and, as a manufacturer of custom-made products, fulfil our obligation, to monitor the products put on the market.

With regard to the UDI (Unique Device Identification) – a system planned by the EU for the identification and registration of medical devices – this will only be required for Class I medical devices from 26.05.2025 in accordance with Article 27(4) in conjunction with Article 123 f of the MDR. Information regarding the UDI introduction at FIOR & GENTZ will follow at a later date.

We look forward to continuing our good and successful cooperation.

Kind regards,