Custom-made devices:

The MDR (formerly MDD) is a European law regulating the production, distribution and service of class I - III medical devices. The MDR came into force in May 2017 and its mandatory application takes effect from 26 May 2021. The MPG will subsequently be replaced by the MPDG and until then will be described by the MPAnpG-EU draft legislation (medical devices amendment law).

Custom-Made Devices:

Article 2, No. 3, MDR: „[…] 'custom-made device' means any device specifically made in accordance with a written prescription of any person authorised by national law by virtue of that person's professional qualifications which gives, under that person's responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs. “

Procedure for custom-made devices according to MDR Annex XIII:

- Setting up a declaration
  - o Name & address of the manufacturer, and of all manufacturing sites
  - o Data necessary for the identification of the device
  - o Declaration that the device was made for a particular patient (name, acronym or number of the patient for identification)
  - o Name of the person who prescribed the device in question and who under national law is authorised to do so through their professional qualification.
  - o Specific features of the device as given in the prescription
  - o Declaration of compliance with the basic requirements according to Annex I
- Availability for national authorities of the documentation which contains the constitution, production and benefit of the device for assessment of the requirements of the prescription
- Measures for the production process for compliance of the documentation with the produced device
- Retention of the declaration for at least 10 years
- The service provider checks and documents the downstream phases after production according to Annex XIV part B and carries out any necessary corrections
- Notification of serious occurrences according to article 87, section 1

eurocom practical guide on the theme of insole blanks:

“With an insole blank which has to be further processed in a technically qualified way according to specific stipulations in the prescription, the specific medical purpose applies only to the custom-made device. The general purpose that the insole blank serves the production of a custom-made product is in any case not sufficient for the assumption of an immediate medical purpose of the insole blank and thus a medical device with a CE marking.”

Conclusion: The health care technician further processes the blanks individually for each customer according to a medical prescription, so that they become a custom-made device.

More documents: https://schein.de/de/download/mdr.html

MDR - Medical Device Regulation (2017/745/EG)

The MDD / MPG (medical device law) has been in force for more than 20 years. The Schein Orthopaedic Service KG has fulfilled all the requirements of the MDD /MPG since it came into force and is now switching to the MDR. The MDR (formerly MDD) is a European law regulating the production, distribution and service of class I - III medical devices. The MDR came into force in May 2017 and its mandatory application takes effect from 26 May 2020.

Medical products (CE):

All medical devices from the Schein Orthopaedic Service KG firm that can be supplied directly to the customer, such as the LucRo, MyGeneration or Post-OP shoes for example, have been marked by us with the CE symbol. All devices have been tested according to the MDR Annex I and are compliant with this.

Insole blanks (no CE):

All Novaped insole blanks from the Schein Orthopaedic Service KG firm are seen as material for the production of custom-made devices and are thus not marked with a CE symbol. All devices are nonetheless tested according to the MDR Annex I. The health care technician further processes the blanks individually for each customer in accordance with details in a medical prescription, so that they become a custom-made device.

Custom-made devices (no CE):

All medical devices that are individually custom-made must be assessed and documented by the manufacturer (or service provider) according to Annex III and MPAnpG (amendment law)-EU (formerly MPG).

Test process according to MDR Annex I (2017/745/EG)	
Shoes (LucRo, MyGeneration, Post-OP)	Insole blanks (Novaped)
Risk management plan	Risk management plan
Quality management system	Quality management system
Post-Market-Surveillance / Post Market Clinical Follow-Up	Post-Market-Surveillance / Post Market Clinical Follow-Up
Clinical assessment	Clinical assessment
Technical documentation	Technical documentation
Declaration of conformity	Declaration of conformity
Marking	Marking
- Unique Device Identifier (UDI)	- **No** Unique Device Identifier (UDI)
- CE-symbol	- **No** CE-symbol

Information at your disposal	
Shoes (LucRo, MyGeneration, Post-OP)	Insole blanks (Novaped)
QM Zertifikat nach ISO 9001:2015	QM ISO 9001:2015 certification
Declaration of conformity	Clearance certificate for the materials
Instructions for use	Processing guidelines
Clearance certificate for the materials	Implementation of the prescription – insole sector (eurocom)
Quality assurance agreement	One-pager custom-made devices