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Combination of Prosthetic Components, in Compliance with the MDR

Dear Business Partners,

We are currently encountering different interpretations in the market regarding the use of prosthetic components from different manufacturers in a prosthesis. We would like to support you regarding maximum action safety and want to offer you answers to the following questions that you may have in this context:

- **What should be considered when using prosthesis components with regard to the MDR?**

- **Is the combination of components from different manufacturers generally permissible and compliant with the MDR?**

In order to answer these questions, it is necessary to compare the basic safety and performance requirements of the MDR with the safety requirements of the previous MDD.

Comparison of Basic Safety and Performance Requirements According to the MDR with the Requirements of the Previous MDD

Some extensions and specifications have been made in the MDR.

At the same time, however, it is interesting to note that, contrary to evaluations that claim the opposite, the **MDR does not(!) tighten the specifications** regarding the combination of components from different manufacturers in a prosthesis!

Rather, the requirements for prosthetic components (medical devices) used in leg prostheses, which were already required by the MDD in a comparable form, also apply under the MDR. These include the following derived requirements:

- Use components only according to their intended purpose
- The use of tested individual components with CE marking does not release technicians from their obligation to check the component combination within their means for suitability, proper assembly and safety.
- For components with different maximum loads, the maximum load of the weakest component applies to the entire prosthesis
- For components with different activity levels, the activity level of the component with the lowest activity applies to the entire prosthesis

As was already the case in the MDD, the MDR also requires a declaration of conformity of the respective manufacturer for the medical devices placed on the market by the manufacturer.

Declaration of Conformity from a Manufacturer of Prosthetic Components

Manufacturers are required to declare the conformity to the requirements of the MDR 2017/745 for those products that are Class 1 products according to annex VIII MDR 2017/745 -Rule 1.

The declaration of conformity of each manufacturer is a basic prerequisite for the use of the corresponding component for a leg prosthesis by an orthopedic technician.
This prerequisite must be met, regardless of whether components from one or from more suppliers are to be used in a prosthesis.

The basic recommendation (also already in the past) is to use components that meet the requirements of DIN EN ISO 10328.

DIN EN ISO 10328

The application of DIN EN ISO 10328 (Structural Testing of Lower-Limb Prostheses) is a "**voluntary means** of meeting the essential safety and performance requirements". Prosthetic components, such as structural components, feet or locking systems, can be tested for their static and dynamic load capacity within defined weight classes.

This means that the application of DIN EN ISO 10328 is **voluntary** for manufacturers of prosthetic components. However, the application of DIN EN ISO 10328 **makes sense** for statically and dynamically loaded components, as it tests the maximum load capacity and permanent load capacity of a component under uniform conditions and allows for a verifiable statement to be made.

To offer you the greatest possible safety, Teufel decided for all load-bearing components to sell only components that have successfully passed this test back in 2010.

The use of components tested in accordance with DIN EN ISO 10328 thus offers you safety for the prostheses you build.
If you combine components from different manufacturers that have been tested in accordance with DIN 10328, this does not necessarily mean that these components are compatible with each other, but it does mean that the load and activity information given are comparable in principle.

In the event of damage, it is also of advantage to be able to refer to the use of tested components when communicating with the responsible authorities (e.g. BfArM).

Conclusion:
As did the MDD in the past, the MDR does not exclude the use of components from different manufacturers in a prosthesis.

Irrespective of whether components from one or more manufacturers are used, the given requirements must be met by the manufacturer (declaration of conformity) or are advisable (DIN EN ISO 10328 Test).

In the event of damage, each manufacturer is responsible and liable for the components they place on the market.

On the part of the service provider (orthopedic technician), the selection of the fitting parts from one or more manufacturers must always take into account the suitability (including weight limit, activity level) for the user of the prosthesis.

Please feel free to contact us at any time if you have any questions.

Best regards from Wangen,

Wilhelm Julius Teufel GmbH