



May 2021

Declaration of No Objection for Materials (Raw Materials)

of the

Wilhelm Julius Teufel GmbH
Robert-Bosch-Str. 15
73117 Wangen

We hereby confirm that the raw materials of the range of materials of the Wilhelm Julius Teufel GmbH are suitable to be used to manufacture of medical devices.

According to the definition of their intended purpose, raw materials on their own are not medical devices. Rather, they are intended for use on or in medical devices which are manufactured as custom products or that are assembled as Class 1 medical devices on which adaptations are made which were designated as permissible by the respective manufacturer of the product.

Due to this, there has to be no MDR-compliant CE marking on the raw materials themselves.

For the raw materials offered by us, an assessment and evaluation have been carried out in accordance with DIN EN ISO 10993, taking into account the intended use for orthopedic purposes.

When using the raw materials, it is mandatory to follow their application instructions in order to ensure the intended use and the harmlessness according to the intended purpose of the material. This includes, for example, considering the specified processing temperature (e.g. for upholstery and sheet materials) or specified mixing ratios (e.g. for casting resins and hardeners).

The safety data sheets of the products are available and can be requested by you at any time.

This declaration of no objection is valid for all products in our range of materials, provided that they are stored and processed in accordance with the product labeling and/or the relevant processing instructions.

Wangen, 18.05.21

Ort, Datum / Lieu, date /
Luogo, data / Place, date

ppa. Christoph Thiel (QM)

Name und Funktion / Nom et fonction /
Nome e funzione / Name and function