Manufacturer Information on the Scope of Training-Dependent Authorisation for Medical Devices: Corticobasal® Implants & Strategic Implant®

The manufacturer authorisation documents participation in a product-specific training course provided by the manufacturer and confirms that the specialist in question is familiar with the safe use of the above-mentioned implant systems.

In accordance with their intended purpose and instructions for use, the implants are intended exclusively for use by appropriately trained dental / implantology specialists. The manufacturer provides training for this purpose; successful qualification can be verified by means of a certificate of authorisation.

Scope of Manufacturer Authorisation / Application in Terms of Intended Use

The use of implants (in accordance with their intended purpose and instructions for use) refers in particular to the following activities:

- Consulting patients
- Drawing up treatment plans
- Inserting implants
- Prosthetic restoration of implants
- Follow-up treatment (even over many years)
- Other services related to treatment with the above-mentioned medical devices

Product-Specific Expertise in Expert Assessments

Special product-specific knowledge is required for expert assessments of treatments with the aforementioned implant systems.

A manufacturer authorisation valid at the time of treatment is suitable proof of such knowledge.

If no such authorisation is available, the product-specific expertise of the assessor should be verifiably documented in another way.

Information on the Legal Situation (93/42/EEC / EU MDR / German MPDG)

The implant systems mentioned are / will be either

1. CE certified in accordance with Directive 93/42/EEC on medical devices (MDD) or

2. CE certified in accordance with Regulation (EU) 2017/745 on medical devices (MDR).

According to both the MDD (93/42/EEC) and the MDR, the CE marking means that the manufacturer has submitted technical documentation including a clinical evaluation and, depending on the risk class, a notified body has assessed conformity with the essential safety and performance requirements.

For products that have been certified on the basis of the MDD ("legacy devices"), the transitional provisions of the MDR (Art. 120 MDR) apply. According to these provisions, MDD-certified products may, under certain conditions, continue to be placed on the market and used during the extended transition periods until the transition to MDR certification has been completed.

In Germany, the MDR is accompanied by the Medical Devices Implementation Act (MPDG).

Technical documentation and clinical evaluation shall include, in particular:

- Clinical data within the scope of clinical evaluation,
- scientific literature and publications,
- safety and performance certificates,
- a documented intended purpose and information on safe use.

The CE marking confirms that the product complies with the relevant European requirements (MDD or MDR) and is suitable for the intended purpose specified by the manufacturer.

However, the assessment of whether a specific treatment has been carried out lege artis always depends on the indication, patient selection and clinical implementation in each individual case.

Additional formal "scientific recognition" beyond CE conformity assessment cannot be demanded across the board for CE-compliant medical devices. Rather, assessments in individual cases must relate to the specific application, indication and available evidence.