

EC-CERTIFICATE

DESIGN EXAMINATION

This is to certify that the quality management system of

Albomed GmbH

Hildebrandstrasse 11, Schwarzenbruck, 90592, Germany

for design and manufacture of

Certificate No: 2385C03210501
Issue Date: 25/05/2021
Original Approval: 25/05/2021
Valid until: 26/05/2024
References: W 001 2385 01
W 001 2385 02

HTCert is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification

Injections of Hyaluronate Intra-Articular Max Gel with Niacinamide for orthopedic usage.

Further details are given overleaf

conforms to the provisions of the Council Directive 93/42/EEC.

The certificate is based on the result of the examination of the submitted design dossier according to Annex II, Section 4, of the Directive. Any changes which could affect conformity with the essential requirements of Directive 93/42/EEC, or with the conditions prescribed for use of the product must receive further approval from HTCert. For marketing of the products, a Full Quality Assurance System Certificate according to the requirements of Annex II, Section 3, of Council Directive 93/42/EEC is required.

For and on behalf of HTCert

GEORGE PAPPOUS Managing Director FILIPPOS KOTTIS
Certification Director

number 2803

p 1/11