

EC Declaration of Conformity

Company:	FRECOMA B.V.
Address:	Ordelven 9 5056 DC Berkel-Enschot The Netherlands
Text/no.	Regulation (EC) No. 1907/2006 – Registration, Evaluation, Authorization and restriction of Chemicals (REACH)
Product identification:	Concerning products as listed in Annex 2021.1.A1
Classification:	93/42/EEC

Frecoma B.V. declares under sole responsibility as per article 11 (5) and annex VII the conformity (compliance to basic requirements) of the attached (Annex 2021.1.A1) mentioned products with the guidelines for medical products 93/42/EEC (EC 2007/47/EC [M5]) for the validity of two years, which means until March 1st, 2023.

The products are classified by Frecoma as medical products Class I (as per rule 5 in annex IX)

Place: Berkel-Enschot, The Netherlands
Date of issue: March 1st, 2021

Signed:

Name:
Function:

Rob. F.C. de Wit
Managing Director



Annex 2021.1.A1

DURAFIT SMOOTH

40.20.5 Durafit Smooth

DURAFIT SEMI-PERFORATED

4020.4 Durafit semi-perforated

DURAFIT GLOSS

40.20.5 Durafit Gloss

DURAFIT PLUS

40.20.2 Durafit Plus
40.20.3 Durafit Plus Semi-perforated

DURAFIT CONDUCTIVE

40.20.51510-51810 Durafit Smooth
40.20.41510-40810 Durafit Semi-perforated

DURAFIT CERAMIC

40.20.5154 - 5224 - 5464 Durafit Ceramic