C&M MedTech

Vi hjälper dig från idé till färdig produkt

C&M MedTech.
Totalpartner inom konstruktionsplaster för medicintekniska applikationer

Vi hjälper dig från idé till färdig produkt

Carlsson & Möller är ett av Sveriges ledande företag inom konstruktionsplaster och polymera material med mer än 60 års material- och applikationskunnande.

C&M MedTech är en avdelning inom Carlsson & Möller inriktad på konstruktionsplaster för medicintekniska applikationer. C&M MedTech svarar för rådgivning och teknisk support samt har resurser för att tillverka prototyper inom medicintekniska områden.

Vi har en modern maskinpark för avancerad bearbetning och tillverkning i korta och långa serier under rutiner som säkerställer en ren produktion utan kontamineringsrisker.

Vi lagerför ett brett sortiment av klassade och godkända material för medicintekniska applikationer från internationellt ledande tillverkare med ursprungscertifikat för full spårbarhet i alla led.

Carlsson & Möller i ingår i Indutrade.

CARLSSON & MÖLLER

Tillsammans skapar vi nya möjligheter

Material biocompatibility tests overview*

TESTS (1)(2) / MATERIALS
KETRON® PEEK-CLASSIX™ LSG white
KETRON® PEEK-CA30 LSG
KETRON® PEEK-GF30 LSG blue (RAL 5019)
KETRON® PEEK LSG natural/black
RADEL® PPSU LSG black
ULTEM* PEI LSG natural
PSU LSG natural
PC LSG natural
ACETRON® LSG

● = This test was carried out and the material passed the test.

NT= Not Tested

1. All tests were run on test specimens machined from rod diameter 50 mm shortly after manufacture.

2. Quadrant EPP performs testing on its Life Science Grades in order to facilitate evaluation by its customers of their biocompatibility with regard to the requirements applicable to the specific use of the finished product. Quadrant EPP does not possess expertise in evaluating the suitability of its tested materials for use in specific medical, pharmaceutical, or biotechnological applications. **It remains the customer's sole responsibility to test and assess the suitability of Quadrant's Life Science Grades for its intended applications, processes and uses.**

	1. Cytotoxicity Ref.: ISO 10993-5 and USP <87> Biological Reactivity Tests, In Vitro Elution Test	2. Sensitization Ref. ISO 10993-10, Magnusson & Kligman Maximization Method	3. Intracutaneous Reactivity Ref.: ISO 10993-10 and USP <88> Biological Reactivity Tests, In Vivo - Intracutaneous Test	4. Systemic Toxicity (acute) Ref.: ISO 10993-11 and USP <88> Biological Reactivity Tests, In Vivo - Systemic Injection Test	5. Implantation Test Ref.: USP <88> Biological Reactivity Tests, In Vivo -Implantation Test (7 days)	5. Human blood compatibility Ref.: ISO 10993-4, Indirect Hemolysis (in vitro)	6. USP-Physicochemical Tests for Plastics Ref.: USP<661> Containers, Ultra Pure Water extract, 70°C/24h	7. Heavy metal content (mg/kg) Testing the content of cadmium, chromium, leadand mercury by means of ICP-MS	USP Class VI (conclusion from tests 3, 4 and 5)
	●	●	●	●	●	●	●	●	●
	●	●	●	●	●	●	●	●	●
	●	●	●	●	●	●	●	●	●
	●	●	●	●	●	●	●	●	●
	●	●	●	●	●	●	●	●	●
	●	●	●	●	●	●	●	●	●
	●	●	●	●	●	●	●	●	●
	●	●	●	●	●	●	●	●	●
	●	NT	NT	NT	NT	NT	●	●	NT(3)

Quadrant Engineering Plastic Products makes no warranties or representations whatsoever that its materials are manufactured in accordance with the quality standards appropriate and necessary for materials intended for use in implantable medical device applications and in applications that are essential to the restoration or continuation of a bodily function important to the continuation of human life.

Quadrant's Life Science Grades should not be used for applications involving medical devices that are intended to remain implanted in the human body continuously for a period exceeding 24 hours (30 days*), or that are intended to remain in contact with internal human tissue or bodily fluids for more than 24 hours (30 days*). They should not be used either for the manufacture of critical components of medical devices that are essential to the continuation of human life.

: '30 days' applies to KETRON® PEEK-CLASSIX LSG white only.

3) Please note that the virgin, natural coloured POM Copolymer resins used in the manufacture of all ACETRON® LSG-stock shapes meet the requirements of USP Class VI (according to biocompatibility tests carried out on behalf of the resin suppliers), and that active Drug Master Files (DMF) on these resins are filed in the DMF-Database of the American Food and Drug Administration (FDA).

*)The tests are provide by Quadrant

QUADRANT

CARLSSON & MÖLLER

Tillsammans skapar vi nya möjligheter

AB Carlsson & Möller, Box 22161, 250 23 Helsingborg

Tel: 042-25 38 00, info@c-m.se

www.c-m.se