

EC DECLARATION OF CONFORMITY



Manufacturer: KOEK Biyoteknoloji Biyomühendislik ve Medikal Hizmetleri Sanayi ve Ticaret Anonim Şirketi Ege Serbest Bölgesi Şubesi.

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R&D Office: Dokuz Eylül Üniversitesi İnciraltı Yerleşkesi DEPARC Sağlık Zeytin Binası Mithatpaşa Cad. 56/20- 215 Balçova / İZMİR

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Product Name: Microfluidic Sperm Sorting Chips- Sperm Separation Device

Model: FERTILE® (MFU1), ZyMöt™ ICSI (ZIH0002) & FERTILE PLUS® (MF11) ZyMöt™ Multi (850µl)(ZMH0850) & FERTILE ULTIMATE® (MF13), ZyMöt™ Multi (3ml) (ZMH3000)

GMDN Code: 17987 - Filtration system, semen

Class and Rule: Class IIa Rule 2

Conformity Assessment Rule : Annex II Section 3

The Directors and Manufacturers: Koek Biotechnology, Bioengineering and Medical Services Industry & Trade Inc. located at Dokuz Eylul University Inciralti Campus DEPARC Health Olive Building Mithatpasa Str. No:56/20/215 Balçova-Izmir, Turkey, and Koek Biotechnology, Bioengineering and Medical Services Industry & Trade Inc. Egean Freezone Branch Office located Zafer Sb. District Nilufer Str. Egean Freezone ESBAS B Blok Apt. No:29/4 Gaziemir/Izmir, Turkey Herewith, declare that the filtration system, semen, known with the trade mark Microfluidic Sperm Sorting Chips Model FERTILE® (MFU1), ZyMöt™ ICSI (ZIH0002) & FERTILE PLUS® (MF11) ZyMöt™ Multi (850µl)(ZMH0850) & FERTILE ULTIMATE® (MF13), ZyMöt™ Multi (3ml) (ZMH3000)are Class IIa rule 2 devices and they manufactured in conformity with EU Directive 93/42 EEC, Annex II Section 3.

Used Standards: AASTM F1929-98, EN 1041+A1, EN 556-1, EN 62366-1, EN 868-6, EN ISO 10993-1, EN ISO 10993-10, EN ISO 10993-13, EN ISO 10993-5, EN ISO 11137-1, EN ISO 11137-2, EN ISO 11607-1/A1, EN ISO 11607-2, EN ISO 11607-2/A1, EN ISO 13485, EN ISO 14155, EN ISO 14644-1, EN ISO 14644-2, EN ISO 14644-3, EN ISO 14644-4, EN ISO 14644-5, EN ISO 14644-6, EN ISO 14644-7, EN ISO 14644-8, EN ISO 14644-9, EN ISO 14937, EN ISO 14971, EN ISO 15223-11.

ISO 13485:2016 Certificate No / Date: 2021/MDQMS/10149/01 – 06 April 2024

Notified Body Information: Kiwa Certification Services Inc. ITOSB 9. Str. No:15 Tepeoren Area, Tuzla, Istanbul-TURKEY

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Notified Body Number: 1984

Certificate Number: 1984-MDD-17-461

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Name: Selcuk KILINC, MD (General Manager & Branch Office Manager)

KOEK BIYOTEKNOLOJİ BİYOMÜHENDİSLİK VE MEDİKAL
HİZ. SAN. VE TİC. A.Ş. EGE SERBEST BÖLGEŞİ ŞUBESİ
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Sign