EC Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

This is to certify that following IVD (In-Vitro Diagnostics) products:

Labosel and Debooglu and Debomed plastic medical and laboratory consumables listed in the attached Device Schedule,

Classified as: 'all other IVD Medical Devices` according to Annex I rules,

Manufactured by: **Debooğlu Inş. Mim. Tar. Ve Gıda A.Ş.**
Antakya Organized Industrial Zone, Cakallı Mah. 14 Nolu Yol, No:1 Belen, Hatay, Turkey, 31350

1. Comply with all essential requirements (Annex I) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.
2. Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:
   a. Availability of the thechnical documentation set in Annex III (section 3), allowing the assessment of the conformity of the product with the requirements of the Directive.
   b. The manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate fort he products manufactured (Annex III section 4).
   c. The manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).
3. Debooğlu A.Ş. has a Quality System in place based on ISO 13485:2016
4. This Declaration of Conformity is signed below, certifying that the requirements of Annex I and Annex III have been met and documented.

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Date: 11.01.2022

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Mehmet H. Debooğlu
General Manager (Bsc Engineering)

Document: 30.1905.GS31

Labosel™ / DeboMed™
Debooglu AS

Debooğlu A.Ş.

Device Schedule

Labosel™ and DebMed™ includes the following consumables.

Name	Detail
Automatic Pipette Tips	Yellow: 5 – 200 uL, Blue: 100 – 1000 uL
Microcentrifuge Tube (Eppendorf)	1.5 mL, with lid
Test Tube (Polystyrene)	5 mL 12x75 mm cylindrical bottom
Test Tube (Polystyrene)	10 mL 16x100 mL conical bottom
Test Tube Caps	For 12x75 mm and 16x100 mm tubes
Urine Specimen Containers	Sterile and Non-Sterile
Urine Specimen Containers	With Pochette and Not sterilized
Gaita/Stool/Faeces Containers	With spoon and screw cap, Sterile and Non-Sterile
Gaita/Stool/Faeces Containers	50 mL, pink
Centrifuge Tube (Falcon Tube)	15 mL, screw cap, Polypropylenec, Sterile and Non-Sterile
End of Schedule	

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