

**Medical and Public Health Services Cyprus Medical Devices Competent Authority** 

File No: 5.23.005.13.5

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13 July 2020

**Demophorius Ltd** 

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Limassol, Cyprus

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Subject: Registration of persons responsible for placing on the Market Medical Devices according to Directive 93/42/EEC and Regulation 598/2003 of Republic of Cyprus

I am instructed on behalf of the Cyprus Medical Devices Authority to inform you that Manufacturer Name:- Demophorius Ltd, located at Manufacturer Address:-196 Archibishop Makarios III Avenue 3030, Limassol, Cyprus has been added to the Medical Devices Manufacturers Registry as the manufacturer of the products: - Demotek Latex, Vinyl & Nitrile examination gloves, pre-powdered/powder-free, non sterile

Classification of the concerned devices:- Class I.

Your registration is based upon your declaration on your application forms dated 02/06/2020 and means that you should now be operating under the Medical Devices Directive 93/42/EEC and Regulation 598/2003 of Republic of Cyprus for the products you asked us to register, by fully complying with the essential requirements, CE marking these products or labelling them as such.

Please inform us of any changes to the company information, or to the technical file of the products before its implementation. Additional editions of products or modifications of the products that are not included in the technical file are not considered as approved by the Competent Authority to be placed on the market.



If you stop placing devices on the market you should inform us so that we can amend our records.

It is noted that the Competent Authority may change its decision in the event that new information is brought to its attention.

The Medical Devices Competent Authority of Cyprus is at your disposal for any further clarifications.

(Cr.Valianti)

for Cyprus Medical Devices
Competent Authority