

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1077517-1

Manufacturer: Lansinoh Laboratories Saglik
Gerecleri Tasarim San. Tic. Ltd. Sti.
Zafer SB Mahallesi Gündüz Sk. No:13
Ege Serbest Bölgesi Gaziemir
35410 Izmir
Turkey

Products: Electric Breast Pumps, Sterile Colostrum Collectors - Closed Systems
for Colostrum Collection

Replaces EC Certificate number HD 1077517-1 dated 2020-07-20

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 28231606 008

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Jaroslaw Pyclik
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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.