LinScan diode laser system

Its Usage status over the world (As of September, 2019)

The status of the approval Acquirement for the device over the countries	United States (approved by FDA in 2018 as K180518)、EU and South Korea. It has obtained the approval in over 20 countries worldwide.
The list of serious side effects could possibly induce by the usage of the device as noted on its instruction for use. (If None, list the information used when applied to FDA)	The following side effects and complications have been reported in treatments with the same or similar intended use in the literature and can therefore occur also in treatments with the LinScan: ・Erythema ・Blister formation ・Edema ・Pigmented lesions (lentigines) and freckles may bleach or disappear ・Light Pain ・Postinflammatory hyperpigmentation ・Hypopigmentation ・Scarring ・Herpes simplex ・Purpura ・Hyperhidrosis (increased sweating) ・Bromhidrosis (strong smell and excessive sweating) ・Leukotrichia (White hair)
Total number of the device delivered over the world.	Around 100
Total number of patients or treatment cases	Grand total 300,000 cases estimated (since 2017)

The Side effect report (cases that are reported to the MHLW)	None
The Manufacturer	GME German Medical Engineering GmbH Grimmstrasse 23 90491 Nuremberg, Germany

Name of the company: GME German Medical Engineering

Signature and date: Stefan Schulze (Managing Director), Oct 8, 2019

※日本語訳

機器名	LinScan diode laser system
機器の欧米各国における承認取得情報	米国（FDA 2018～）、EU、韓国、他世界２０か国以上
機器の添付文書に掲載している重大な副作用一覧　（ない場合、FDA など承認取得時の内容）	紅斑、水膨れの形成、浮腫、色素沈着、そばかす（その後消える可能性大）、軽度の痛み感、炎症後の色素沈着、色素低下、傷跡、ヘルペス、紫斑、多汗症、臭汗症、白斑症
機器の世界における納入台数	約 100 台
累計患者数または治療数	治療数約 300,000 件
副作用報告（各国の厚生労働省などに提出しているもの）	なし
製造元	GME German Medical Engineering GmbH