

Declaration of Conformity

Name of the Declarer : SAN ESU GYPSUM CO., LTD.

Address of the Declarer : 13th Floor Daidouseimei Esaka Bldg., 1-23-101
Esaka-cho, Suita, Osaka, 564-0063 JAPAN

Subject of declaration : NEW ALGISTAR NORMAL

The subject of the declaration declares that it meets the following requirements.

1. Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Medical Devices and In-vitro Diagnostic Reagents

(Ministerial Ordinance on QMS)

(MHLW Ministerial Ordinance No. 169 on December 17, 2004)

2. ISO 13485 : 2016

Medical device - Quality management system - Requirements for regulatory purposes

Date of issue : July 06, 2022

Place of issue : SAN ESU GYPSUM CO., LTD.
Main Factory Quality Assurance Department

The issuer : Quality Assurance Manager Akiho KAMIWAKI

Responsible person : Chief Executive Officer

Jiro Miyatake

