

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 : NEWGYSTONE

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)

Date of issue : July 06, 2022

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

The issuer : Quality Assurance Manager Akiko KAMIWAKI

Responsible person : Chief Executive Officer

Ju Inuyatoko

