

EU Declaration of Conformity

Company name: Prenger Healthcare B.V.
Lange Kleiweg 14
2288 GK, Rijswijk, The Netherlands

Manufacturer: Alliance Rubber Products Sdn. Bhd.
Lot 2716 & 2720, MK 7
Kawasan Perindustrian Bukit Panchor
14300 Nibong Tebal, Pulau Pinang, Malaysia

European Representative: Obelis s.a.
Bd. Général Wahis 53
B-1030 Brussels, Belgium

Object of declaration: Prenger 1020 Latex Disposable Gloves 5.9G
Model: 1020
Intended purpose: Latex Examination Gloves intended to be worn by healthcare practitioners to protect patient and user from cross-contamination.
GMDN code: 47172
UMDNS code: 11882
Basic UDI: 955586710LGPFQS

Classification (MDR, Annex VIII): Class I, Rule 1.

Conformity Assessment Route: EU DECLARATION OF CONFORMITY following the Annex II + Annex III + Article 19 of MDR (EU) 2017/745.

General applicable regulations, directives:

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Applied standards, common specification, guidance:

EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN ISO 374-1:2016+A1:2018, EN420:2003+A1:2009, EN ISO 374-2:2014, EN ISO 374-5:2016, EN 16523-1:2015+A1:2018, ISO 16604:2004

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the EU Regulation and Standards.

All supporting documentations are retained under the premises of the manufacturer.

Alliance Rubber Products Sdn. Bhd. is exclusively responsible for the declaration of conformity.

Prenger Healthcare B.V.:

Name: Mr. Peter Prenger
Title: Founder
Signature:

Alliance Rubber Products Sdn. Bhd.:

Name: Mr. Chua Hooi Koon
Title: Managing Director
Signature:

Place, date: 1-1-2021

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