F. BOSCH

MEDIZINTECHNIK

GERMANY

Instructions for use

Model: FBGLVE-1021 to 1025, FBGLVE-1031 to 1035, FBGLVE-1041 to 1045, FBGLVE-1051 to 1055

F. Bosch International Limited

10/F, Lee King Industrial Building, 12 Ng Fong Street, San Po Kong,

Kowloon, Hong Kong

Web: www. fbosch.com.hk Email: info@fbosch.com.hk

EC REP MDSS GmbH

Schiffgraben 41, 30175 Hannover, Germany

Issued on April 2020

Instructions for use
Glove for single use Compliant with MDR 2017/745, PPE Regulation (EU) 2016/425, EN 420, EN455, ISO15223-1 and ISO 374.

Instructions for use are to be used in combination with the specific product related information on each product packaging. The gloves are sold as a bundled unit within the shipping carton. In case this bundled unit is dismantled and products are sold separately, the distributor must ensure that the instructions for use are accompanied with each separate unit.

The gloves are classified as Personal Protective Equipment (PPE) Category III according to PPE Regulation (EU) 2016/425 and classified as Medical Device Class I according to Medical Device Regulation (MDR) 2017/745, which have been shown to comply with these regulations through the applicable harmonised European standards. The gloves meet the EN/ISO standards shown on each specific packaging.

The gloves are **single-use only** and to be disposed after contamination.

Intended use:

Latex powdered/powder free examination/protective glove is a disposable device intended for medical purposes that is worn on the examiners hand to protect the patient and the examiner for cross contamination. Non-sterile examination/protective gloves are intended for dentistry, diagnostic and therapeutic procedures, clinical examination and medical examination except surgery.

Special Precautions for use:
Always check the gloves for possible mechanical damage, e.g. holes or tears, before use. Do not use damaged gloves.
Glove length is appropriate to the end use where the risk to the wrist area is minimal.
Avoid contact with chemicals such as oils, strong acids, strong alkalis, and organic solvents that may cause deterioration or damage to gloves.
If there have any serious incident occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Ingredients / Hazardous ingredients:
The gloves might contain ingredients which are known to possibly cause skin irritations or allergic reactions with sensitised persons. Stop usage in case of allergic reactions and consult a healthcare professional if required. Check warning information on specific packaging carefully. Formulation available on request.

Storage instructions:
Keep storage area cool, dry and dust free, avoid ventilation and storage close to photocopy equipment. Protect gloves against ultraviolet light sources, sunlight and oxidizing agents. Store in original packaging in a dry and dark place at the temperatures between 10^{o}C to 30^{o}C.
Product life time: 5 years

Explanation of standards and pictograms: (please check the information on the back of each box)

ISO 374-1 Type A / B / C EN ISO374-1: 2016 Permeation levels are based on breakthrough times as follows:

ABCDEFGHIJKLMNOPST

Performance level	1	2	3	4	5	6
Minimum breakthrough times (mins)	>10	>30	>60	>120	>240	>480

Type A = chemical breakthrough time >30 minutes against at least 6 chemicals from the list
Type B = chemical breakthrough time >30 minutes against at least 3 chemicals from the list

Type C = chemical breakthrough time >10 minutes against at least 1 chemical from the list
Test chemicals:
A = Methanol / B = Acetone / C = Acetonitrile / D = Dichloromethane / E = Carbon disulphide / F = Toluene /
G = Diethylamine / H = Tetrahydrofuran / I = Ethyl acetate / J = n-Heptane /
K = Sodium hydroxide 40 % / L = Sulphuric acid 96 % / M = Nitric acid 65 % / N = Acetic acid 99 % /
O = Ammonium hydroxide 25 % / P = Hydrogen peroxide 30 % / S = Hydrofluoric acid 40 % /
T = Formaldehyde 37 %

EN 374-4:2013 - The degradation (in %) indicates the change in puncture resistance of the gloves after exposure to the respective challenge chemical.

This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals. The chemical resistance has been assessed under laboratory conditions from samples taken from the palm only and relates only to the chemical tested. It can be different if the chemical is used in a mixture. It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on temperature, abrasion and degradation. When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves. Before usage, inspect the gloves for any defect or imperfections.

ISO 374-5:2016 - Tested for resistance to penetration according to EN 374-2:2014


Virus

Tested for resistance to penetration by blood-borne pathogens according to ASTM F1671.
Resistance to bacteria and fungi – pass
Resistance to virus – pass
The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.

CE **XXXX** XXXX = Identification number of notified Body responsible for the EU type examination and supervising ongoing conformity.


For single-use only and must not be reused.

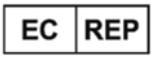

Before usage read instructions for use carefully.

EN 420:2003+A1:2009


Use by Date

Batch Code (The lot number would be appeared in the box of the package)


Date of Manufacture



Authorized Representative in the European Community


Manufacturer

Serial Number

Non-Sterile


Temperature Limit

Contin or presence of Natural Rubber Latex

Do not contain Powder

Contain Powder

Medical Device

Content of the package:
Primary Package: 100pcs per box
Secondary Package: 10x100pcs per carton

UDI Carrier would be printed in primary and secondary product package based on the regulatory requirement when regulation request the product is required to have the UDI carrier code.

Instruction Use:
After usage, dispose of in accordance with all national and local regulations.

1) Always wash hands before donning the gloves and use a new pair every time.
2) Take out gloves from their original box.
3) Ensure appropriate glove selection for specific task and ensure the glove is of the correct size.
4) Touch only a restricted surface of the glove corresponding to wrist (at the top edge of the cuff).
5) Don the first glove and take the second glove with bare hand and touch only a restricted surface of the glove corresponding to the wrist area.
6) To avoid touching the skin of the forearm with the glove hand, turn the external surface of the glove to be donned on the folded fingers of the gloved hand, thus permitting to don the second hand
7) Once both hands are donned, they should not touch anything else that is not defined by indications and conditions for glove usage.
8) Change gloves before beginning a different task to avoid cross contamination.
9) Pinch one glove at the wrist level to remove it, without touching the skin of the forearm, and peel away from the hand, allowing the glove to turn inside out.
10) Hold the removed glove in the donned hand and slide the fingers of the un-gloved hand inside between the glove and the wrist. Remove the second glove by rolling it down the hand and fold into the first glove.
11) Dispose the removed glove and wash hands thoroughly.
12) Not intended to be used as a chemical barrier.
    The shelf life is normally advised to be five full years. Check the original dispenser instructions for details.