



Zhonghong Pulin Medical Products Co.,Ltd.

Add: West Industrial Park, Luannan County, Tangshan City, 063500, Hebei, China

Tel:0086-315-4167693 Fax:0086-315-4168700

DECLARATION OF APPROVAL FOR THE USE OF PRODUCT WITH FOOD

The Manufacturer:

Zhonghong Pulin Medical Products Co.,Ltd

West Industrial Park, Luannan County,

Tangshan City, 063500, Hebei, China

Represented by (EU, Switzerland): CURADEN AG, Amlehnstrasse 22, 6010 Kriens, Switzerland

Declaration for the following model/gloves

Nitrile VELVET GRIP blue (Premium)

Relevant category "elastomers and rubber"

meets the following regulations:

General principles of Europe Resolution Res AP(2004) 4 on rubber, EC Regulations 1935/2004 and 2023/2006 relating to good Manufacturing Practice for materials and articles intended to come into contact with food.

All ingredients, starting monomers and additives used in the production of this glove are compliant with: - all positive lists - all relevant Specific Migration Limits (SML) or restrictions of the applicable EU food legislation.

Global Migration Data:


Simulants used:	Test condition	Result(s) [mg/kg]	Max. allowed limit
Ethanol (W/V) 10%	2 hours/ 70°C	<5.0	60
Acetic acid (W/V) 3%	2 hours/ 70°C	<5.0	60
Ethanol (W/V) 95%	2 hours/ 60°C	<5.0	60
Iso-octane	0,5 hours/ 40°C	<5.0	60

According to EN 1186, the analytical tolerance for simulants of foods containing water, alcohol and acids is 1 mg/dm², for simulants of fatty foods 3 mg/dm².

Storage instructions: Protect from direct sunlight, store in a cool and dry place in the original packaging. Store away from sources of ozone. If the gloves are stored properly according to the above instructions, their performance and properties will not be significantly reduced. For gloves that may be affected by aging or storage, the use-by date is stated on the packaging materials.

Signature:

中红普林医疗用品股份有限公司
Zhonghong Pulin Medical Products Co., Ltd.



Date: March 16, 2022