

# DECLARATION OF CONFORMITY

## A. General Information:

**Name of Medical Device:** ... POWDER  
FREE NITRILE Examination Gloves, Latex  
Examination Gloves, NON-STERILE

**Trade\ Brand name:** WIRKS LIFE

**Model:** ... WGA-02

**Name and address of manufacturer:**  
... WIRKSAM PHARMA PVT. LTD.

Unit-I : H-519/A, RIICO Ind. Area Jhotwara  
Extn-II, Sarna Dunga, Jaipur-302012  
(Rajasthan)

(ISO : 13485:2016 and GMP Certified  
company)

### Type of medical device:

General medical device ☒

In-vitro medical device ☐

**Self Life:** 3 Years From Date of  
Manufacture.

**Storage:** The Gloves Shall Maintain Their Property When Stored in a dry Condition at  
temperature not higher than 30°C.

### Class of medical device:

Class A ☐

Class B ☒

Class C ☐

Class D ☐

**Intended use:** Widely used in Medical  
Food Processing, Examination, Machinery,  
Cleaning, Family Hygienic Protection ETC.

## B. QUALITY MANAGEMENT SYSTEM

Conformity to ISO 13485: 2016 ☒

Conformity to other quality management  
system:

Yes ☒

No ☐

### Standards used to assure compliance:

NITRILE Examination Gloves- ISO 374-  
5:2016

Latex Examination Gloves -ISO-11193-1-  
2008

## DECLARATION OF CONFORMITY:

I hereby declare that the medical device mentioned above complies with the  
regulatory requirements for medical devices has been classified appropriately and  
conforms to the Essential Principles of Safety and Performance.

Date: 5/2/2021

