

EU DECLARATION OF CONFORMITY

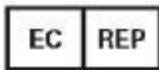
Doc No.: D-MDR-02/10-A04PHD

Identification of the Legal
Manufacturer & Address



: Blue Sail Medical Co., Ltd
: No. 21 Qingtian Road, Qilu Chemical Industrial Park,
Zibo, Shandong 255414 China

European Authorized
Representative



:Lotus NL B.V.
: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague,
Netherlands
:Email: peter@loutsnl.com

Brand Name

Digitil V

Distributed By

Paul Hartmann AG

Basic UDI-DI

: 69332655MD01002471763A powder free

Product & Identification

: **Disposable Vinyl Examination Gloves, Powder Free**

Intended purpose of the
product:

The Disposable Vinyl Examination Gloves is a disposable product intended for
medical purposes that is worn on the examiner's hand or finger to prevent
contamination between patient and examiner.

GMDN code and product:

: **47176 Vinyl examination/treatment glove, non-powdered**

EMDN code:

: **T01020201 GUANTI NON CHIRURGICI IN VINILE**
EXAMINATION / TREATMENT GLOVES, VINYL

Manufacture SRN Number:

: CN-MF-000001139

REP SRN Number:

: NL-AR-000000121

Risk Classification:

: Class 1, Non-sterile, no measuring function and not surgical instrument

We hereby declare that the above mentioned devices comply with the European Medical Device Regulations
(EU) MDR 2017/745. The EU declaration of conformity is issued under the sole responsibility of the
manufacturer.

Conformity Assessment
Procedure

: Article 52(7) and
: Annex VIII, 4.1 Rule 1, Non-invasive device, and/or
: 5.1 intended for transient use, Rule 5 of invasive device.

Conformity Route

: Self-Declaration

Relevant Harmonized
Standards:

: EN ISO13485:2016

EN 455 Standard
Test Report

: EN 455-1:2020/A2:2024, EN455-2:2024, EN455-3:2015
EN455-4:2009

Quality System Certificate

Powder Free :
70.418.24.022.04A-00,70.418.24.022.04B-00
70.418.24.022.04C-00,70.418.24.022.04D-00
70.418.24.022.04E-00

Identification of the person
authorized to sign on behalf of
the Legal Manufacturer:

: ISO 13485 Certificate No: Q5 062837 0012 Rev. 06
: ISO 13485 Certificate Body: TUV SUD Product Service GmbH
: Issued Date: 01 Aug 2025 Valid Date: 31 Jul 2028
: Signed by:

: Print Name: Robin Liu
: Title: Quality Director Location:Shandong,China Date:01 Aug 2025