



DECLARATION OF CONFORMITY CERTIFICATE

WE,

UNIQUE INTERNATIONAL S.A.S.

**Cra 19a No. 196-23
Bogotá, Colombia- S.A.**

Hereby declare in our own responsibility, that our products:

UNIQ MALE AND FEMALE CONDOMS

Meet the essential requirements of the Council Directive 93/42/EEC of 14 June, 1993 concerning Medical Devices, amended by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007,

Conformity Assessment Procedure

According to annex II of the Council Directive named above

Classification

Class IIB

Notified Body

MedCert GmbH

Pilatuspool 2, D-20355 Hamburg

Identification number: 0482

Reference Standards

Applicable standards are part of the Technical Documentation and can be looked up upon request

Validity

Based on the Quality System and Quality Management Certification:
11/July, 2024

We hereby appoint **mdi Europa GmbH**, Langenhagener Str.71. 30855 Hannover - Langenhagen, Germany, to act as European Authorized Representative as explicitly defined in Article 1, § 2(g) of Directive 98/79/EEC.

Place and date: Bogotá, November 03, 2021

*Diego Gonzalez
Technical Director and Quality*

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