



cryomade^o

cryomade°

Cryosurgery Solutions

Your trusted supplier for N2O

We made sure our gas is high performing & medical grade pure.



In order to achieve desired results, pureness of N2O is key. This is why we have spent years making sure our cartridges are corrosion free and only filled with the purest N2O.

Our specialized filling unit filtering upon fill and making sure no particles get through.



cryomade°

Mademed sprl.
www.mademed.eu

cryomade°

Safe & Pure

A better design for longer life

Our high precision particle size controlling valve and strong body can withstand 4 times the required internal pressure assures only pure N2O is released.



We made sure the inner surface of the cannister is electro plated with corrosion resisting elements to ensure no undesired particles are formed.

Moreover, the impact resistant carry case assures safe delivery and storage of your cartridges.



CE certified and manufactured at facilities that comply with ISO 13485 and TPED regulatory requirements.

Mademed sprl.
www.mademed.eu

Smart Packaging





Elegant

Secure & Sturdy





SAFETY

EU-Declaration of Conformity



cryomade^o

Manufactured at Gama Arařtırma Patent Tasarım ve Endüstriyel Ürünler San. Tic. Ltd. Şti.
Eseñehir mah. Kuru sk. No:28 Ümraniye İstanbul Turkey

under our sole responsibility that the products

Cryogenic Applicator Start Kit & Cartridge Set
M1.04.B & M1.05.B

*is in conformity with the Medical Device Regulation
Annex-V Directive 93/42 EEC union harmonized
legislation according to report*

M.6158.01

issued by the authorized body headquarters and subsidiary

KWA Deutschland GmbH
Grüner Deich 1
D - 20097 Hamburg



KWA Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cadde No:15 Tepeören
Tuzla İstanbul

and is in valid until 27 May 2024

*References to the relevant harmonized standards used, including the date of the
standard, or references to the other technical specifications, including the date of the
specification, are in relation to conformity declared above.*

Document No: 1984 - MDD - 21 - 782

Authorized Body No: 1984

Istanbul 2020-05-11

Place and date (yyyy-mm-dd)

GAMA Arařtırma Patent
Tasarım ve End. Ür. San.
Tic. Ltd. Şti.
Eseñehir Mah. Kuru Sok.No: 28
Tel: 0212 415 88 88 Ümraniye-İSTANBUL
Sangazi V.D. 388 050 0144

Bekir Kuralkan
General Manager

EC Certificate

**Production Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-V**

Certificate Number: 1984-MDD-21-782

We hereby declare that an examination has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex-V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation.

Organization:**GAMA ARAŐTIRMA PATENT TASARIM VE ENDÜSTRİYEL
ÜRÜNLER SANAYİ TİCARET LİMİTED ŐİRKETİ**

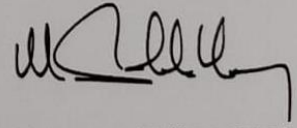
ESENŐEHİR MAH. KURU SK. NO:28, ÜMRANİYE, İSTANBUL, TURKEY

Product: Cryogenic Applicator Start Kit & Cryogenic Cartridge Set
Model Number: M1-04.B, M1-05.B

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number: M.6158.01
Expiry Date: 27 May 2024

Kiwa Belgelendirme Hizmetleri A.Ő. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984



MuhteŐem Gökhan Yücel
Head of Notified Body

11 May 2021, Istanbul, Turkey

Technical
Universal
Verification



CERTIFICATE

This Certificate has been awarded to:

GAMA ARAŞTIRMA PATENT TASARIM VE ENDÜSTRİYEL ÜRÜNLER SAN. TİC. LTD. ŞTİ.

ESEŖEHİR MAH. KURU SK. NO:28 ÜMRANIYE

İSTANBUL - TURKEY

In Recognition of the Organisation's Management System which complies with:

ISO 9001 : 2015

For the Scope of Activities described below:

SALES AND TECHNICAL SUPPORT OF EARPLUGS, NEBULIZER, CRYOGENIC TUBE/NOZZLE,
PRODUCTION AND SALES OF HELMET WITH VISOR

Certificate No : 1160

Reissue Date :-

Date of Audit : 08.08.2018

Expiry Date : 01.10.2019

Date of Registration : 02.10.2018

Technical Universal Verification

This document is valid for 3 years provided that the management system is well maintained and surveillance audits are performed regularly. After performing the surveillance audits certificate will be reissued. The current status of this certificate can be viewed via www.techcert.com.tr web site. This certificate is a property of Technical Universal Verification Certification and Training Services Co., Ltd. Thus, this certificate has to be returned if required by property owner. United Accreditation Foundation (UAF) is an accreditation body whose headquarters is located in the United States of America, which is a member of International Accreditation Forum (IAF).



Technical Universal Verification
Belgelendirme ve Eğitim Hizmetleri Ltd. Şti.
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CERTIFICATE

This Certificate has been awarded to:

GAMA ARAŞTIRMA PATENT TASARIM VE ENDÜSTRİYEL ÜRÜNLER SAN. TİC. LTD. ŞTİ.

ESENŞEHİR MAH. KURU SK. NO:28 ÜMRANİYE
İSTANBUL - TURKEY

In Recognition of the Organisation's Management System which complies with:

ISO 13485 : 2016

For the Scope of Activities described below:

PRODUCTION SALES AND TECHNICAL SUPPORT OF EARPLUGS,
NEBULIZER AND CRYOGENIC TUBE/NOZZLE

Certificate No : 4098

Reissue Date :-

Date of Audit : 09.08.2018

Expiry Date : 01.10.2019

Date of Registration : 02.10.2018

Technical Universal Verification

This document is valid for 3 years provided that the management system is well maintained and surveillance audits are performed regularly. After performing the surveillance audits certificate will be reissued. The current status of this certificate can be viewed via www.techcert.com.tr web site.

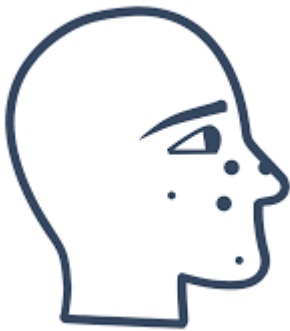
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Multiple Use



Oxidation Free

N₂O can oxidize un-treated surfaces over time. This can impact purity of your gas. This is why Cryomade Cartridges are manufactured with high quality galvanization internal surface plating.

Our galvanization plating process covers internal surfaces of our cartridges after they are formed into their shape, which assures plating is not damaged and holds its integrity.

With Cryomade shelf life of your cartridges are secured.

Release Pressure

Our digitally controlled filling station ensures every bottle filled with minimum of 50 bar pressure. Making sure you get the same performance out of every bottle.

Safety

Although Cryomade cartridges operate between 50 - 55 bar pressure range, we have designed them to withstand 250 bar pressure with thicker carbon steel body.

You can be rest assured you are safe while using Cryomade.

Valve

In order to deliver a long shelf life and a stable output, we have designed a unique dome valve. The dome seal has a larger contact surface compared to standard o-ring seals, reducing the risk of gas leaks and flow instability.

Filtered at every point

Due to the oxidizing nature of N₂O, all surfaces gas comes in contact with, from origin containers to final bottle, have to be controlled. Our multi-stage filtered (< 5 Micron) filling station and valve design not only filters the gas on the way in but also on the way out.

We make sure our gas meets breathable purity at every level of the production and filling process.

Although, Cryomade cartridges are created for cryosurgery applications we have gone above and beyond to make sure they meet breathable level of purity.

Shelf Life & Traceability

Combination of end to end purity and tracibility practices assure our cartridges hold their performance for their complete 3 year shelf life.

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