

**SAO Y BẢN CHÍNH**  
Ngày 20 tháng 4 năm 2022

# EU Declaration of Conformity

(Manufacturer's Declaration)

**GIÁM ĐỐC**  
CÔNG TY TRÁCH NHIỆM HỮU HẠN DỊCH VỤ TRỌNG TÂM  
TRẦN QUANG ĐỨC  
PHỐ HỒ CHÍ MINH

**Manufacturer**

Fountain Head Marketing Inc. Dba Romet Electronic Larynx  
14410 Saratoga Pass, San Antonio, Texas 78254 USA  
Telephone 1.210.858.5189  
Fax 1.210.858.9608  
Single Registration Number (SRN): US-MF-00000924

This declaration of conformity is issued under the sole responsibility of Fountain Head Marketing Inc. Dba Romet Electronic Larynx.

The Manufacturer hereby declare that the listed medical device(s) in the end of this document are in conformity with the essential requirements and other relevant requirements of the listed Regulations, Directives and Common Specifications. All supporting documentation is retained at the premises of the manufacturer.

**Authorized Representative**

**EuropeCert**  
Alsstr. 97, 41063  
Monchengladbach, Germany

Tel. +49(0) 2161990883  
mail to: support @Europecert.eu  
Single Registration Number (SRN): DE-AR-000004974

**Applicable Harmonized Standards**

EN 60601-1-2:2015, BS EN 60601-1:2006+A12:2014, EN 1041:2008, EN ISO 15223-1:2016

**GMDN code:**

30076

**Classification:**

Class I as per rule 13 of Annex VIII Regulation (EU) MDR 2017/745 for medical devices.

**Conformity assessment route:**

The Manufacturer uses the following procedures for the CE-labeling of their products according to the Regulation MDR 2017/745:

Class I: EC conformity declaration according to Annex II & Annex III

**This document has no expiration date**

Signed in San Antonio, Texas 2021-06-02  
on behalf of Fountain Head Marketing Inc.:

Tom Dodson  
President Romet Electronic Larynx

**Exclusive Distributor For Vietnam**

**Quang Duc Hearing Services Ltd**  
384 Cach Mang Thang 8, Ward 4,  
Tan Binh District  
Ho Chi Minh City  
Vietnam  
Ph: 84 28 3844 6415



**Products Covered by this declaration of conformity.**

	<b>Description</b>	<b>Item Number</b>	<b>GMDN Code</b>
<b>PRODUCTS</b>	Artificial Larynx Device	R700	30076
	Artificial Larynx Device	R600	30076
	Artificial Larynx Device	R120	30076
	Artificial Larynx Device	R210	30076
	Artificial Larynx Device	R310	30076
<b>ACCESSORIES</b>	Repair Top Section for Model R120	RA001	30076
	Repair Top Section for Model R310 / R210	RA002	30076
	Shower Guard	RSGP	30076
	Stoma Cover	RSC	30076
	Stoma Cover with Extended Neck	RSCX	30076
	Stoma Cover, Turtleneck	RTNSC	30076
	Foam Filters	RFFL2	30076
	Pack of (2) 9V Li-On Batteries with Charger	C200	30076
	Dual Post 9V Li-On Charger 110V / 220V	C150	30076
	9V Li-On Battery (Qty 1)	B970	30076
	Round 7.2V NiMH Battery (Qty 1)	B7.280	30076
	USB Charger with Micro USB Cord	C600	30076
	Oral Adapter with (10) Clear Tubes	C215	30076

# EU Declaration of Conformity

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## Manufacturer

Fountain Head Marketing Inc. Dba Romet Electronic Larynx  
14410 Saratoga Pass, San Antonio, Texas 78254 USA  
Telephone 1.210.858.5189  
Fax 1.210.858.9608  
Single Registration Number (SRN): US-MF-000009241

This declaration of conformity is issued under the sole responsibility of Fountain Head Marketing Inc. Dba Romet Electronic Larynx.

The Manufacturer hereby declare that the listed medical device(s) in the end of this document are in conformity with the essential requirements and other relevant requirements of the listed Regulations, Directives and Common Specifications. All supporting documentation is retained at the premises of the manufacturer.

## Authorized Representative

**EuropeCert**  
Alsstr. 97, 41063  
Monchengladbach, Germany  
  
Tel. +49(0) 2161990883  
mail to: support @Europecert.eu  
Single Registration Number (SRN): DE-AR-000004974

## Applicable Harmonized Standards

EN 60601-1-2:2015, BS EN 60601-1:2006+A12:2014, EN 1041:2008,  
EN ISO 15223-1:2016

## GMDN code:

30076

## Classification:

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**Ho Chi Minh City**  
**Vietnam**  
**Ph: 84 28 3844 6415**



**Products Covered by this declaration of conformity.**

	Description	Item Number	GMDN Code
<b>PRODUCTS</b>	Artificial Larynx Device	5 R700	30076
	Artificial Larynx Device	4 R600	30076
	Artificial Larynx Device	1 R120	30076
	Artificial Larynx Device	2 R210	30076
	Artificial Larynx Device	3 R310	30076
<b>ACCESSORIES</b>	Repair Top Section for Model R120	RA001	30076
	Repair Top Section for Model R310 / R210	RA002	30076
	Shower Guard	RSGP	30076
	Stoma Cover	RSC	30076
	Stoma Cover with Extended Neck	RSCX	30076
	Stoma Cover, Turtleneck	RTNSC	30076
	Foam Filters	RFFL2	30076
	Pack of (2) 9V Li-On Batteries with Charger	C200	30076
	Dual Post 9V Li-On Charger 110V / 220V	C150	30076
	9V Li-On Battery (Qty 1)	B970	30076
	Round 7.2V NiMH Battery (Qty 1)	B7.280	30076
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	Oral Adapter with (10) Clear Tubes	C215	30076