

Medicor Europe AG  
Wingepark 5B 101  
3110 Rotselaar Belgium  
IBAN: BE31 3630 9764 1755  
SWIFT: BBRUBEBB  
EORI: BECH000085

# Medicor Europe AG

Official partner of  Nemoto

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Fax: +32 (0) 16 22 44 26  
Email: [info@medicor-international.com](mailto:info@medicor-international.com)  
Website: [www.medicor-international.com](http://www.medicor-international.com)  
VAT nr: BE0844106173

Rotselaar February 20<sup>th</sup> 2020

## Letter of authorization

We Medicor Europe AG having a registered office at Wingepark 5B/101 3110 Rotselaar Belgium and international authorized agent of:

Nemoto Kyorindo Co. Ltd, 2-27-20 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan

And

Coeur Inc. Coeur, 100 Physicians Way Suite 200, Lebanon, TN 37090, USA

hereby assign "Intermed SRL", having a registered office at Str. Tighina 65, Chisinau MD-2001, Moldova, as authorized representative in correspondence with the conditions of directive 93/42/EEC, 98/79/EEC and 90/385/ECC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Sincerely yours,



Hassan Hajji

Managing Sales Director

Medicor Europe AG

*Medicor Europe AG*  
Bellevueweg 11  
CH-6300 Cham Switzerland  
Vat Nbr : BE 0844106173  
Eori nr : BECH000085  
Iban : BE31363097641755  
Switzerland BBRUBEBB





By Royal Charter

# EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

**No.** CE 01848  
**Issued To:** **Coeur, Inc.**  
**209 Creekside Drive**  
**Washington**  
**North Carolina**  
**27889**  
**USA**

In respect of:

**The manufacture of sterile and non-sterile front load syringes, non sterile retrofit kits, sterile and non-sterile angiographic and CT syringes, and fluid delivery products.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk -  
Medical Devices

First Issued: **1998-03-16**

Date: **2018-03-12**

Expiry Date: **2023-03-15**



...making excellence a habit™

Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.  
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A member of BSI Group of Companies.



COEUR, INCORPORATED  
 100 Physicians Way  
 Suite 200  
 LEBANON, TN 37090  
 WEBSITE: www.coeurinc.com

## Product Summary Sheet

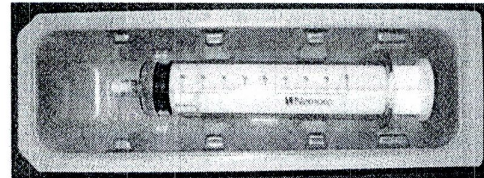
Catalog/Product/Reference#: SYPET - 100

Description: Disposable Nemoto 100mL CT, PET Syringe

### Components / Materials

Part		Component		Material
Name	Qty/Unit	Description	Qty/Ea	
100mL Syringe	1	Barrel	1	Natural PET
		Plunger	1	White Polypropylene
		Plunger Jacket	1	Black Synthetic Rubber
		Dust Cap	1	White Polyethylene

### Photo



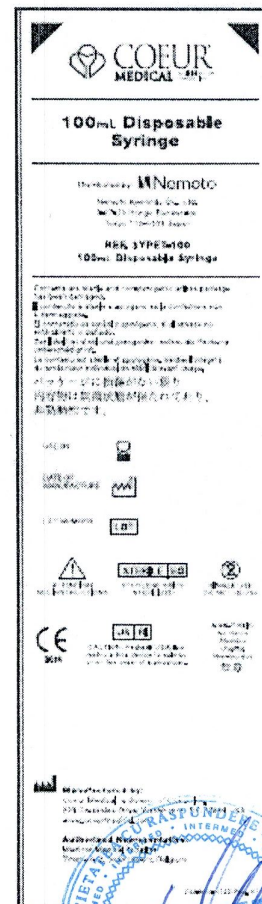
Label

### Packaging / Sterilization

Attribute	Material/Detail
Lid	White Tyvek
Rigid Tray	Natural Polystyrene
Quantity per Case	50
Approx. Weight per Case	6.6kg (14.5lbs)
Shipper Dimensions	56.18cm x 34.92cm x 29.36cm (22 <sup>1</sup> / <sub>8</sub> " x 13 <sup>3</sup> / <sub>4</sub> " x 11 <sup>9</sup> / <sub>16</sub> " )
Sterilant	ETO

### Technical Characteristics

Attribute	Detail
Pressure Rating	2.1MPa (300psi 21kgf/cm <sup>2</sup> )
Intended Use	To deliver, in low-pressure injection systems, contrast media to the vascular system for diagnostic purposes
Injector with Which Product is to be Used	Nemoto Dual Shot Alpha Injector Nemoto Dual Shot GX Injector Nemoto A300 Injector Nemoto A60 Injector



This summary sheet has been developed based on an approved manufacturing specification.

Title: VP, Quality & Regulatory Affairs

Signature: [Handwritten Signature]

Date: 02/01/11





## Product Summary Sheet

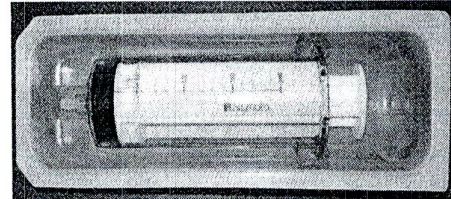
Catalog/Product/Reference#: **SYPET - 200**

Description: **Disposable Nemoto 200mL CT, PET Syringe**

### Components / Materials

### Photo

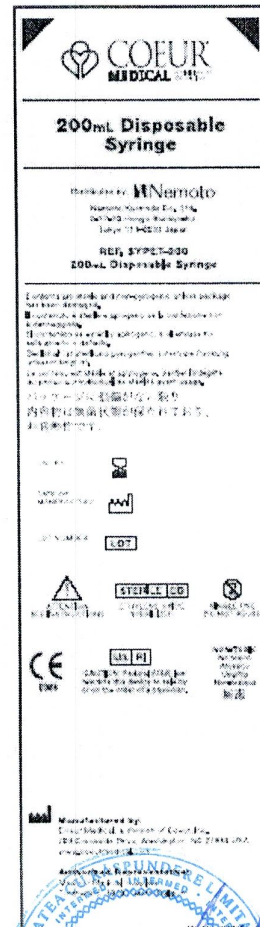
Part		Component		Material
Name	Qty/Unit	Description	Qty/Ea	
200mL Syringe	1	Barrel	1	Natural PET
		Plunger	1	White Polypropylene
		Plunger Jacket	1	Black Synthetic Rubber
		Dust Cap	1	White Polyethylene



### Packaging / Sterilization

### Label

Attribute	Material/Detail
Lid	White Tyvek
Rigid Tray	Natural Polystyrene
Quantity per Case	50
Approx. Weight per Case	9.5 kg (21lbs)
Shipper Dimensions	56.18cm x 34.92cm x 31cm (22 <sup>1</sup> / <sub>8</sub> " x 13 <sup>3</sup> / <sub>4</sub> " x 12 <sup>13</sup> / <sub>16</sub> " )
Sterilant	ETO



### Technical Characteristics

Attribute	Detail
Pressure Rating	2.1MPa (300psi 21kgf/cm <sup>2</sup> )
Intended Use	To deliver, in low-pressure injection systems, contrast media to the vascular system for diagnostic purposes
Injector with Which Product is to be Used	Nemoto Dual Shot Alpha Injector Nemoto Dual Shot GX Injector Nemoto A300 Injector Nemoto A60 Injector

This summary sheet has been developed based on an approved manufacturing specification.

Title: VP, Quality & Regulatory Affairs

Signature: [Handwritten Signature]

Date: 02/10/11





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 100 Physicians Way, Ste. 200  
 LEBANON, TN 37090  
 WEBSITE: www.coeurinc.com

## Technical Summary Sheet

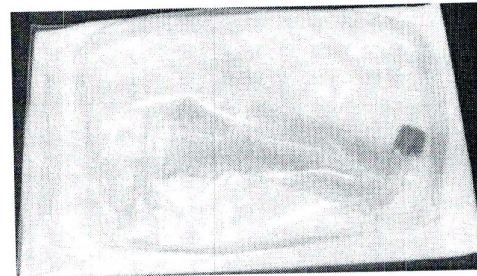
Catalog/Product/Reference#: **C405-0060**

Description: **Coeur 60" (1500mm) Coiled Extension Line**

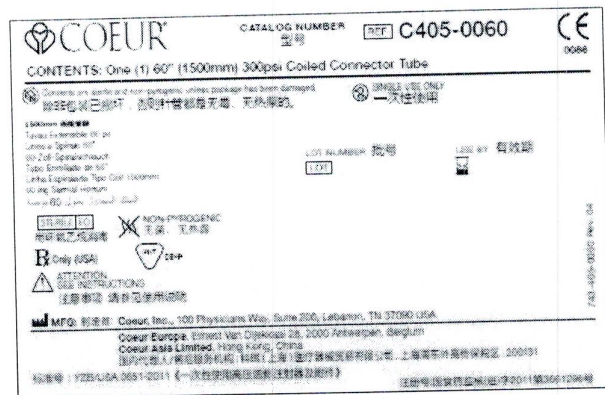
### Components / Materials

### Photo

Component	Qty/ Unit	Material
1.77mm/0.070" ID x 3.25mm/0.128" OD Tubing	1	1500mm / 60" Clear PVC
Female Luer	1	Clear Polycarbonate (PC)
Male Luer	1	Clear PC
Universal/Female Dust Cap	1	White HDPE or PC
Male Dust Cap	1	Blue Polypropylene or ABS



### Label



### Packaging / Sterilization

Attribute	Material / Detail
Top Web	White Tyvek with Blue Ink
Bottom Web	Natural EVA/Surlyn Blend
Quantity / Case	100 (2 inner boxes of 50)
Approx. Weight / Case	3.6kg (8 lbs)
Shipper Dimensions	51.6cm x 28.4cm x 19.4cm (20 <sup>5</sup> / <sub>16</sub> " x 11 <sup>3</sup> / <sub>16</sub> " x 7 <sup>5</sup> / <sub>8</sub> " )
Sterilant	ETO

### Technical Characteristics

Attribute	Detail
Pressure Rating	300psi
Intended Use	To be used as an interface between Coeur CT Syringes or other syringes and needle catheters for use in delivering contrast media to the vascular system.







COEUR, INCORPORATED  
100 Physicians Way, Ste 200  
LEBANON, TN 37090  
WEBSITE: www.coeurinc.com

## Technical Summary Sheet

Catalog/Product/Reference#: **C405-1559**

Description: **Coeur 1500mm Extension Y- Line with 1 Check Valve**

### Components / Materials

Component	Qty/ Unit	Material
Tubing	1	1500mm / 60" Clear PVC
	1	76.2mm / 3" (or 4")* Clear PVC
	1	177.8mm / 7" (or 5")* Clear PVC w / Blue Stripe
Female Luer	2	Clear Polycarbonate (PC)
Male Luer	1	Clear PC
Y-Connector	1	Clear ABS or PVC
Check Valve	1	Translucent Purple PC and Blue Silicone
Universal/Female Dust Cap	1	White HDPE or PC
Male Dust Cap	2	(1) Blue & (1) Natural Polypropylene

\* The short extensions of the Y-Line are either a combination of 3" & 7" or 4" & 5".

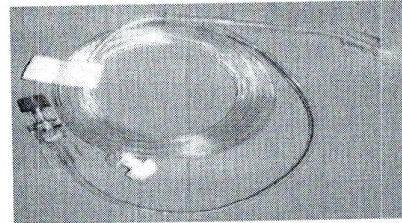
### Packaging / Sterilization

Attribute	Material / Detail
Pouch	White Tyvek and Clear Polyethylene
Quantity / Case	100 (2 Inner boxes of 50)
Approx. Weight / Case	3.6kilos (8lbs)
Shipper Dimensions	53.34cm x 30.48cm x 17.78cm (20 <sup>5</sup> / <sub>16</sub> " x 11 <sup>3</sup> / <sub>16</sub> " x 7 <sup>5</sup> / <sub>8</sub> " )
Sterilant	ETO

### Technical Characteristics

Attribute	Detail
Pressure Rating	300psi
Intended Use	To be used as an interface between Coeur CT Syringes or other syringes and needle catheters for use in delivering contrast media to the vascular system.

### Photo



### Label

	CATALOG NUMBER 型号 REF <b>C405-1559</b>	
CONTENTS: One (1) 60" (1500mm) 300psi Straight Extension Y-Line with Check Valve		
Contents are sterile and non-pyrogenic unless package has been damaged. 除非包装已损坏, 否则针管都是无菌, 无热原的。		SINGLE USE ONLY 一次性使用
1500mm 多路连接箱插 Truse de Pratergerent Erit en 1500 mm, avec 1 Check Valve Prüfung zur Maßnahme in 1500 mm, mit 1 Check Valve 1500mm 300psi 多路连接箱插 Caja de Extensione Unica en 1500mm con 1 Valvula de Control Caixa de extensao com 1 300 mm CV, Valvula de Regulacao 1500mm 300psi 多路连接箱插 1500mm 300psi 多路连接箱插	LOT NUMBER 批号 LOT	USE BY 有效期 
STERILE 灭菌 用环氧乙烷消毒 Only (USA) ATTENTION SEE INSTRUCTIONS 注意事项 请参见使用说明	NON-PYROGENIC 无热原 FFP 0.2µm	Advertised in Mexico 7-22-05-1559-Fluor-G
MFG: 制造商 <b>Coeur, Inc.</b> , 100 Physicians Way, Suite 200, Lebanon, TN 37090 USA <b>Coeur Europe</b> , Ernest Van Dijkstraat 28, 2000 Antwerpen, Belgium <b>Coeur Asia Limited</b> , Hong Kong, China 国内代理人/售后服务机构 科瑞(上海)医疗器械贸易有限公司 上海浦东新区福桥路4号, 200131 标准号 YZB/JUSA 0661-2011 《一次性使用高压注射器及附件》 注册证: 沪食药监械(注)字2011第36011206号		

