EC Design Examination Certificate
Medical Devices Directive 93/42/EEC

*The National Standards Authority of Ireland as a duly designated Notified Body, (identification number **0050**), for the purposes of the European Communities (Medical Devices) Regulations (S.I. No. 252 of 1994)*

HAS EXAMINED THE DESIGN DOSSIER
Submitted by

S.C. ROMPHARM COMPANY S.R.L.

1A Eroilor Street
Otopeni
Ilfov 075100
Romania

For Product Family

Sodium hyaluronate 60mg/3ml and chondroitin sodium sulfate 90mg/3ml sterile solution for injection in prefilled syringe (brand names: Hialurom Hondro, Chondryal Plus, Orthoflex One, Sertobec-Pro, Novaxil Plus, CARTInorm XL CHONDRO, CHONDRO-HYAL, BIOPORT CROSSLINK)

GMDN Code: 44757

CONCLUSION of EXAMINATION:

NSAI have performed an examination of the design dossier relating to the above named product family and conclude that the design complies with the requirements of Directive 93/42/EEC on Medical Devices, Annex II (4)

Registration Number:	**252.979**
Original Approval:	**30 March 2016**
Last Amended on:	**31 August 2022**
Remains valid until:	**18 February 2024**

Signed:

Approved by:
Lisa Donlon
European Medical Device Operations Manager

Approved by:
Dr Majella Geraghty
European Medical Device Operations Manager

CONDITIONS OF VALIDITY:

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner. Approved model numbers are included in the associated attachment

Note: Not valid without a valid Annex II Section 3 Certificate.

Changes which could affect conformity with the essential requirements of Directive 93/42/EEC or with the conditions prescribed for use of the product must receive further approval from NSAI.

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.

Attachment to Certificate 252.979 dated 30 March 2016

This Certificate covers 8 model(s)

Model Reference	Detail
HIALUROM HONDRO	Sodium Hyaluronate 60mg/3ml and chondroitin sodium sulfate 90 mg/3ml, sterile solution for injection in prefilled syringe
ORTHOFLEX ONE	Sodium Hyaluronate 60mg/3ml and chondroitin sodium sulfate 90 mg/3ml, sterile solution for injection in prefilled syringe
CHONDRYAL PLUS	Sodium Hyaluronate 60mg/3ml and chondroitin sodium sulfate 90 mg/3ml, sterile solution for injection in prefilled syringe
SERTOBEC-PRO	Sodium Hyaluronate 60mg/3ml and chondroitin sodium sulfate 90 mg/3ml, sterile solution for injection in prefilled syringe
NOVAXIL PLUS	Sodium Hyaluronate 60mg/3ml and chondroitin sodium sulfate 90 mg/3ml, sterile solution for injection in prefilled syringe
CARTInorm XL CHONDRO	Sodium Hyaluronate 60mg/3ml and chondroitin sodium sulfate 90 mg/3ml, sterile solution for injection in prefilled syringe
CHONDRO-HYAL	Sodium Hyaluronate 60mg/3ml and chondroitin sodium sulfate 90 mg/3ml, sterile solution for injection in prefilled syringe
BIOPORT CROSSLINK	Sodium Hyaluronate 60mg/3ml and chondroitin sodium sulfate 90 mg/3ml, sterile solution for injection in prefilled syringe

Last Amended Date: 31 August 2022
Date of Printing: 5 September 2022

EC Design Examination Certificate
722/2012

*The National Standards Authority of Ireland as a duly designated Notified Body, (identification number **0050**), for the purposes of the European Communities (Medical Devices) Regulations (S.I. No. 554 of 2003)*

HAS EXAMINED THE DESIGN DOSSIER
Submitted by

S.C. ROMPHARM COMPANY S.R.L.

1A Eroilor Street
Otopeni
Ilfov 075100
Romania

For Product Family

Sodium hyaluronate 60mg/3ml and chondroitin sodium sulfate 90mg/3ml sterile solution for injection in prefilled syringe (brand names: Hialurom Hondro, Chondryal Plus, Orthoflex One, Sertobec-Pro, Novaxil Plus, CARTInorm XL CHONDRO, CHONDRO-HYAL, BIOPORT CROSSLINK)

GMDN Code: 44757

CONCLUSION of EXAMINATION:
Complies with the Annex requirements of Regulation 722/2012

Registration Number:	**252.979**
Original Approval:	**30 March 2016**
Last Amended on:	**31 August 2022**
Remains valid until:	**18 February 2024**

Signed:

Approved by:
Lisa Donlon
European Medical Device Operations Manager

Approved by:
Dr Majella Geraghty
European Medical Device Operations Manager

CONDITIONS OF VALIDITY:

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.

Note: Changes which could affect conformity with the essential requirements of Directive 93/42/EEC and/or Regulation 722/2012, or with the conditions prescribed for use of the product must receive further approval from NSAI.

National Standards Authority of Ireland, 1 Swift Square, Santry, Dublin 9, Ireland

Quality System Approval Certificate
Medical Devices Directive 93/42/EEC

*The National Standards Authority of Ireland as a duly designated Notified Body, (identification number **0050**), for the purposes of the European Communities (Medical Devices) Regulations (S.I. No. 252 of 1994)*

APPROVES THE QUALITY SYSTEM APPLIED BY

S.C. ROMPHARM COMPANY S.R.L.

1A Eroilor Street
Otopeni
Ilfov 075100
Romania

to the Product Family

Sodium hyaluronate 60mg/3ml and chondroitin sodium sulfate 90mg/3ml sterile solution for injection in prefilled syringe (brand names: Hialurom Hondro, Chondryal Plus, Orthoflex One, Sertobec-Pro, Novaxil Plus, CARTInorm XL CHONDRO, CHONDRO-HYAL, BIOPORT CROSSLINK)

GMDN Code: 44757

on the basis of examination under the requirements of Directive 93/42/EEC on Medical Devices, Annex II, excluding (4)

*The use of the NSAI Notified Body identification number **0050** in conjunction with CE Marking of Conformance for this product family is hereby authorised.*

Registration Number:	**252.979**
Original Approval:	**30 March 2016**
Last Amended on:	**31 August 2022**
Remains valid until:	**18 February 2024**

Signed:

Approved by:
Lisa Donlon
European Medical Device Operations Manager

Approved by:
Dr Majella Geraghty
European Medical Device Operations Manager

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.
Details of the operational locations included within the scope of this approval can be obtained from NSAI

In the case of a Class III device, this certificate must be supported by a valid design examination certificate

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.