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S.C. Rompharm Company S.R.L. - Romania, Ilfov, 75100 Otopeni, Str. Eroilor, Nr. 1A.
CUI: RO 14399646, RC: J23/1321/2004

Cod formular *Form code*: AC-PcertifDM-58_F2_ed6

DECLARATIE DE CONFORMITATE *DECLARATION OF CONFORMITY*

Nr *No*: 2903202104

Noi, SC Rompharm Company SRL, cu adresa str. Eroilor Nr. 1A, 75100 Otopeni, Ilfov, Romania, reprezentata in tara de destinatie prin distribuitor: Goodwill Pharma Kft., cu adresa/telefon/fax nr : 6724 Szeged, Cserzy M. u. 32, Ungaria,

We, SC Rompharm Company SRL, address Eroilor 1A street, 75100 Otopeni, Ilfov, Romania, in the destination country represented by distributor : Goodwill Pharma Kft., with address/ phone/fax No: 6724 Szeged, Cserzy M. u. 32, Hungary,

Declaram pe proprie raspundere ca : *herewith declare that* :

Produs *Product*: Hialuronat de sodiu 60mg/3ml si Condroitină sulfat de sodiu 90mg/3ml, soluție injectabilă în seringă preumplută

Sodium hyaluronate 60mg/3ml and Chondroitin sodium sulfate 90mg/3ml solution for injection in pre-filled syringe

Nume marca/ Denumire comerciala ***Brand name****/trade name:* **CARTInorm XL CHONDRO**

dispozitiv medical clasa de risc **III**, reguli de clasificare *Medical Device risk class **III** classification rule(s)* :

8	pentru DM ce contin Hialuronat de sodiu *for MD containing Sodium hyaluronate*
8, 13, 17	pentru DM ce contin Hialuronat de sodiu si condroitina sulfat de sodiu *for MD containing Sodium hyaluronate and Chondroitin Sodium Sulfate*

(conform Anexa IX a Directivei 93/42/CEE *according to Annex IX of the Council Directive 93/42/EEC*)
care face obiectul acestei declaratii de conformitate, îndeplineste prevederile Directivei 93/42/CEE pentru dispozitive medicale, transpusa în legislația națională prin Titlul XX din Legea 95/2006 *subject of this declaration, meets the provisions of the Council Directive 93/42/EEC for medical devices as transposed into national law by Title XX from Law 95 /2006 .*
Toate documentele justificative se păstrează la sediul producătorului. *All supporting documentation is retained under the premises of the manufacturer.*

Standardele aplicate *Standards applied* :
MDD 93/42/EEC, EU Regulation 722/2012, EN ISO 13485:2016, EN ISO 15223-1:2016, EN 556-2:2015, EN ISO 13408-1:2015, EN ISO 11737-1:2015, EN ISO 10993-10:2014, EN ISO 14971:2012, EN ISO 13408-2:2011, EN ISO 14155:2011
EN ISO 10993-1:2009/ AC:2010, EN ISO 10993-5:2009, EN ISO 10993-6:2009, EN ISO 10993-11:2009, EN ISO 10993-17:2009, EN ISO 10993-18:2009, EN ISO 14630 : 2009, EN ISO 11138-3:2009, EN ISO 1041:2008, EN ISO 22442-1:2007,
EN ISO 17665-1:2006, EN 556-1:2001, EN 20594-1:1993/AC:1996, European Pharmacopoeia, current edition, Eudralex vol 4

Organismul de certificare, nume/adresa/ numar de identificare ***The Notified Body*** *name/address /identification number,*
Certificate CE numar *CE certificate number* / Certificat de inregistrare in tara de destinatie *Registration certificate No in destination country*
NSAI (National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland) / **CE0050 / 252.979**

Informatii suplimentare legate de produs *Supplementary informations about product*:
Dispozitivul medical a fost testat in conformitate cu Specificația Produsului Finit Nr:
Medical device was tested according the Finished Product Specification No: AC-SPF-hial20mg/ml/condr30mg/ml(CE)

Seria *batch*	Cantitatea eliberata, unitati comerciale *Quantity released, commercial units*	Data fabricației *Date of manufacture*	Data de expirare *Expiry date*	Tara de destinatie *Destination country*	Certificat de analiza nr/data: *Certificate of Analysis no/ date*
2102645	**902**	**02.2021**	**02.2024**	**Ungaria *Hungary***	**0264-hu-5/26.03.2021**

Locul, Data emiterii: OTOPENI, Romania 29.03.2021
Place, Issue data

Numele, functia, semnatura persoanei responsabile MIHAI CRISTINA Qualified Person
Name, position, signature of the responsible person :

ROMPHARM COMPANY 2 14399646 ROMÂNIA