Traducere din limba engleza

OLYMPUS

DECLARATIE DE CONFORMITATE (DEM)

1. Producator OLYMPUS MEDICAL SYSTEMS CORP.
2. Adresa 2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japonia
3. Model OLYMPUS CF-H185L/I
4. Nume produs EVIS EXERA III COLONOVIDEOSCOP
5. Numar serie sau lot CF-H185L : de la 2200001 la
   CF-H185AI : de la 2500001 la

6. Clasificare Clasa IIa

7. Reprezentanti autorizati in UE

Nume Olympus Europa Holding GmbH
Adresa Wendenstr. 14-18 20097 Hamburg, Germania

Prin prezenta declaram ca produsul mai sus mentionat este in conformitate cu cerintele Directivei CE 93/42/CEE (DEM) pe propria responsabilitate in calitate de producator legal. Aceasta Declaratie de Conformitate este valabila pentru echipamentele produse avand seria/numarul de lot de mai sus.

Aceasta declaratie se bazeaza pe: DEM, Anexa II.3

8. Aprobare organism notificat
Emis de catre TUV Rheinland LGA Products GmbH (0197)
Adresa : Tillystrasse 2, D-90431 Nurnberg, Germania

9. Standarde aplicate : A se vedea lista de verificare a cerintelor esentiale pentru produsul mentionat mai sus.

Loc 2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japonia
Semnatura (semnatura indescifrabila)
Nume Susumu Nishina
Functie Manager general
Administrare Calitatii Vanzarilor
Departamentul Reglementare & Asigurarea Calitatii
Data 16/01/2013 (zz.ll.aaaa)

[N-OIS D28001 Anexa 3]

ROMÂNIA
MINISTERUL JUSTIȚIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 22069
TEL: 0745471452

Digitally signed by Grabazei Alexandru
Date: 2023.06.10 10:56:34 EEST
Reason: MoldSign Signature
Location: Moldova

DECLARATION OF CONFORMITY(MDD)

OLYMPUS

1. Manufacturer	OLYMPUS MEDICAL SYSTEMS CORP.
2. Address	2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507 Japan
3. Model	OLYMPUS CF-H185L/I
4. Name of product	EVIS EXERA III COLONOVIDEOSCOPE
5. Serial or Lot No.	CF-H185L: from 2200001 to /CF-H185I: from 2200001 to
6. Classification	Class IIa

7. Authorized representative in EU

Name	Olympus Europa Holding GmbH
Address	Wendenstr. 14-18 20097 Hamburg, Germany

We hereby declare that the above mentioned product complies with the requirements of EC Directive 93/42/EEC(MDD)under the sole responsibility as a legal manufacturer. This Declaration of Conformity is valid in manufactured devices with the above Serial/Lot number.

This declaration is based on : MDD, Annex II.3

8. Notified Body Approval

Issued by	TÜV Rheinland LGA Products GmbH (0197)
Address	Tillystrasse 2, D-90431 Nürnberg, Germany

9. Applied Standards — Refer to the Essential Requirements Checklist for above mentioned product.

Place	2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan
Signature	Nishina
Name	Susumu Nishina
Title	Chief Manager Market Quality Administration Regulatory Affairs & Quality Assurance Department
Date	2013/01/16

[N-OIS D28001 Appendix 3]