

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]



DECLARATION OF CONFORMITY(MDD)

1. Manufacturer	<u>OLYMPUS MEDICAL SYSTEMS CORP.</u>
2. Address	<u>2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507 Japan</u>
3. Model	<u>OLYMPUS CF-H185L/I</u>
4. Name of product	<u>EVIS EXERA III COLONOVideoscope</u>
5. Serial or Lot No.	<u>CF-H185L:from 2200001 to /CF-H185I:from 2200001 to</u>
6. Classification	<u>Class IIa</u>
7. Authorized representative in EU	
Name	<u>Olympus Europa Holding GmbH</u>
Address	<u>Wendenstr. 14-18 20097 Hamburg, Germany</u>

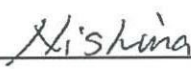
We hereby declare that the above mentioned product complies with the requirements of EC Directive 93/42/EEC(MDD) under the sole responsibility as a legal manufacturer. This Declaration of Conformity is valid in manufactured devices with the above Serial/Lot number.

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

8. Notified Body Approval

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

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

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