



Radio Equipment Directive DoC Table of Contents

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Declaration of Conformity

Directive 2014/53/EU
DoC-1016493

Lumenis Ltd.
Yokneam Industrial Park
Hakidma Street 6,
Yokneam 2069204, Israel

We declare on our sole responsibility that the following radio equipment models are in conformity with the relevant Union harmonization legislation in Directive 2014/53/EU:

AcuPulse DUO (LT-LFS03-SYS-02)
UltraPulse DUO (LT-LFS03-SYS-02)
Lumenis Pulse 100H/50H (LT-LFS03-SYS-06R)
Lumenis Pulse 60H (LT-LFS03-SYS-07)
Lumenis Pulse 30H (LT-LFS03-SYS-09)

The relevant harmonized standards and/or technical specifications which have been applied in relation to this declaration of conformity are:

Directive 2014/53/EU	Standards
Article 3.1a (Safety)	EN 60601-1 EN 50364
Article 3.1b (EMC)	EN 60601-1-2 EN 301 489-1 EN 301 489-3
Article 3.2 (Spectrum)	EN 300 330

Dan O'Callaghan
Name, VP, Regulatory Affairs and Quality

27/July/2022
[Publish Date]
Date

Dodi Reznick
Name, VP, Research & Development

Declaration Validity Date
28/July/2022
[Publish Date]
Date

Declaration Validity Date



Catalog Number	Product Name	Device Type
GA-1000000	AcuPulse DUO	System
GA-1000000CN	AcuPulse DUO CHINA	System
RG-1000000	Refurbish AcuPulse DUO	System
GA-2000000	UltraPulse DUO	System
RG-2000000	Refurbished UltraPulse DUO	System
GA-2006098	Lumenis Pulse 30H with cart	System
GA-2003322	Lumenis Pulse 30H, with cart Japan	System
RG -2006098	Lumenis Pulse 30H with cart, refurbished	System
GA-1008943	Lumenis Pulse 50H, INT	System
GA-1008946	Lumenis Pulse 50H, DOM	System
GA-1008943CN	Lumenis Pulse 50H, China	System
GA-2006378	Lumenis Pulse 60H, 50Hz	System
GA-2006379	Lumenis Pulse 60H, 60Hz	System
GA-1008942	Lumenis Pulse 100H INT	System
GA-1008944	Lumenis Pulse 100H DOM	System
RG-1008944	Lumenis Pulse 100H, DOM, Refurbished	System
RG-1008942	Lumenis Pulse 100H, INT, Refurbished	System
GA-1008942CN	Lumenis Pulse 100H, China	System



Konformitätserklärung

Richtlinie 2014/53/EU

DoC-1016493

Lumenis Ltd.
Yokneam Industrial Park
Hakidma Street 6,
Yokneam 2069204, Israel

Hiermit erklären wir in alleiniger Verantwortung, dass die folgenden Funkanlagenmodelle und Zubehörteile der Richtlinie 2014/53/EU über die Harmonisierung der Rechtsvorschriften der Mitgliedstaaten entsprechen:

AcuPulse DUO (LT-LFS03-SYS-02)
UltraPulse DUO (LT-LFS03-SYS-02)
Lumenis Pulse 100H/50H (LT-LFS03-SYS-06A, LT-LFS03-SYS-06R)
Lumenis Pulse 60H (LT-LFS03-SYS-07)
Lumenis Pulse 30H (LT-LFS03-SYS-09)

In Bezug auf diese Konformitätserklärung wurden die folgenden harmonisierten Normen und/oder anderen einschlägigen technischen Spezifikationen angewandt:

Richtlinie 2014/53/EU	Normen
Artikel 3.1a (Sicherheit)	EN 60601-1 EN 50364
Artikel 3.1b (Elektromagnetische Verträglichkeit)	EN 60601-1-2 EN 301 489-1 EN 301 489-3
Artikel 3.2 (Spektrum)	EN 300 330

Dan O'Callaghan
Name, VP, Regulatorische Angelegenheiten
und Qualität

27/July/2022
[Publish Date]
Datum

Dudi Reznick
Name, VP, Forschung & Entwicklung

Gültigkeitsdatum der Erklärung
28/July/2022
[Publish Date]
Datum

Gültigkeitsdatum der Erklärung



Bestell-Nr.	Produktname	Gerätetyp
GA-1000000	AcuPulse DUO	System
GA-1000000CN	AcuPulse DUO CHINA	System
RG-1000000	Refurbish AcuPulse DUO	System
GA-2000000	UltraPulse DUO	System
RG-2000000	Refurbished UltraPulse DUO	System
GA-2006098	Lumenis Pulse 30H with cart	System
GA-2003322	Lumenis Pulse 30H, with cart Japan	System
RG -2006098	Lumenis Pulse 30H with cart, refurbished	System
GA-1008943	Lumenis Pulse 50H, INT	System
GA-1008946	Lumenis Pulse 50H, DOM	System
GA-1008943CN	Lumenis Pulse 50H, China	System
GA-2006378	Lumenis Pulse 60H, 50Hz	System
GA-2006379	Lumenis Pulse 60H, 60Hz	System
GA-1008942	Lumenis Pulse 100H INT	System
GA-1008944	Lumenis Pulse 100H DOM	System
RG-1008944	Lumenis Pulse 100H, INT, Refurbished	System
RG-1008942	Lumenis Pulse 100H, DOM, Refurbished	System
GA-1008942CN	Lumenis Pulse 100H, China	System



Déclaration de Conformité

Directive 2014/53/UE

DoC-1016493

Lumenis Ltd.
Yokneam Industrial Park
Hakidma Street 6,
Yokneam 2069204, Israel

Il est de notre seule responsabilité de certifier que les modèles suivants d'équipements hertziens sont conformes à la législation d'harmonisation pertinente de l'Union, telle que décrite dans la directive 2014/53/UE:

AcuPulse DUO (LT-LFS03-SYS-02)
UltraPulse DUO (LT-LFS03-SYS-02)
Lumenis Pulse 100H/50H (LT-LFS03-SYS-06A, LT-LFS03-SYS-06R)
Lumenis Pulse 60H (LT-LFS03-SYS-07)
Lumenis Pulse 30H (LT-LFS03-SYS-09)

Les normes harmonisées et/ou les spécifications techniques pertinentes qui ont été appliquées en relation avec cette déclaration de conformité sont les suivantes :

Directive 2014/53/UE	Normes
Article 3.1a (Sécurité)	EN 60601-1 EN 50364
Article 3.1b (Compatibilité électromagnétique)	EN 60601-1-2 EN 301 489-1 EN 301 489-3
Article 3.2 (Spectre)	EN 300 330

Dan O'Callaghan
Nom, VP, Affaires réglementaires et Qualité

27/July/2022
[Publish Date]
Date

Dudi Reznick
Nom, VP, Recherche et Développement

Date de validité de la
déclaration
20/July/2022
[Publish Date]
Date

Date de validité de la
déclaration



Référence catalogue	Nom du produit	Type de dispositif
GA-1000000	AcuPulse DUO	System
GA-1000000CN	AcuPulse DUO CHINA	System
RG-1000000	Refurbish AcuPulse DUO	System
GA-2000000	UltraPulse DUO	System
RG-2000000	Refurbished UltraPulse DUO	System
GA-2006098	Lumenis Pulse 30H with cart	System
GA-2003322	Lumenis Pulse 30H, with cart Japan	System
RG -2006098	Lumenis Pulse 30H with cart, refurbished	System
GA-1008943	Lumenis Pulse 50H, INT	System
GA-1008946	Lumenis Pulse 50H, DOM	System
GA-1008943CN	Lumenis Pulse 50H, China	System
GA-2006378	Lumenis Pulse 60H, 50Hz	System
GA-2006379	Lumenis Pulse 60H, 60Hz	System
GA-1008942	Lumenis Pulse 100H INT	System
GA-1008944	Lumenis Pulse 100H DOM	System
RG-1008944	Lumenis Pulse 100H, INT, Refurbished	System
RG-1008942	Lumenis Pulse 100H, DOM, Refurbished	System
GA-1008942CN	Lumenis Pulse 100H, China	System



Declaración De Conformidad

Directiva 2014/53/UE

DoC-1016493

Lumenis Ltd.
Yokneam Industrial Park
Hakidma Street 6,
Yokneam 2069204, Israel

Declaramos, bajo nuestra responsabilidad exclusivamente, que los siguientes modelos de equipos radioeléctricos y accesorios están en conformidad con la legislación pertinente de armonización de la Unión Europea en la Directiva 2014/53/UE:

AcuPulse DUO (LT-LFS03-SYS-02)
UltraPulse DUO (LT-LFS03-SYS-02)
Lumenis Pulse 100H/50H (LT-LFS03-SYS-06A, LT-LFS03-SYS-06R)
Lumenis Pulse 60H (LT-LFS03-SYS-07)
Lumenis Pulse 30H (LT-LFS03-SYS-09)

Las normas armonizadas pertinentes o especificaciones técnicas que se han aplicado en relación con la declaración de conformidad son las siguientes:

Directiva 2014/53/UE	Normas
Artículo 3.1a (Seguridad)	EN 60601-1 EN 50364
Artículo 3.1b (Compatibilidad electromagnética)	EN 60601-1-2 EN 301 489-1 EN 301 489-3
Artículo 3.2 (Espectro)	EN 300 330

Dan O'Callaghan
Nombre, VP, Asuntos Regulatorios y de Calidad

27/July/2022
[Publish Date]
Fecha

Dudi Reznick
Nombre, VP, Investigación y Desarrollo

Fecha de validez de la declaración
28/July/2022
[Publish Date]
Fecha



Fecha de validez de la
declaración

Número de catálogo	Nombre del producto	Tipo de dispositivo
GA-1000000	AcuPulse DUO	System
GA-1000000CN	AcuPulse DUO CHINA	System
RG-1000000	Refurbish AcuPulse DUO	System
GA-2000000	UltraPulse DUO	System
RG-2000000	Refurbished UltraPulse DUO	System
GA-2006098	Lumenis Pulse 30H with cart	System
GA-2003322	Lumenis Pulse 30H, with cart Japan	System
RG -2006098	Lumenis Pulse 30H with cart, refurbished	System
GA-1008943	Lumenis Pulse 50H, INT	System
GA-1008946	Lumenis Pulse 50H, DOM	System
GA-1008943CN	Lumenis Pulse 50H, China	System
GA-2006378	Lumenis Pulse 60H, 50Hz	System
GA-2006379	Lumenis Pulse 60H, 60Hz	System
GA-1008942	Lumenis Pulse 100H INT	System
GA-1008944	Lumenis Pulse 100H DOM	System
RG-1008944	Lumenis Pulse 100H, INT, Refurbished	System
RG-1008942	Lumenis Pulse 100H, DOM, Refurbished	System
GA-1008942CN	Lumenis Pulse 100H, China	System



Dichiarazione di Conformità

Direttiva 2014/53/UE
DoC-1016493

Lumenis Ltd.
Yokneam Industrial Park
Hakidma Street 6,
Yokneam 2069204, Israel

Dichiariamo sotto la nostra esclusiva responsabilità che i seguenti modelli di apparecchiature radio sono conformi alla legislazione di armonizzazione dell'Unione pertinente della direttiva 2014/53/UE:

AcuPulse DUO (LT-LFS03-SYS-02)
UltraPulse DUO (LT-LFS03-SYS-02)
Lumenis Pulse 100H/50H (LT-LFS03-SYS-06A, LT-LFS03-SYS-06R)
Lumenis Pulse 60H (LT-LFS03-SYS-07)
Lumenis Pulse 30H (LT-LFS03-SYS-09)

Le norme armonizzate e/o le specifiche tecniche pertinenti che sono state applicate ai sensi della presente dichiarazione di conformità sono le seguenti:

Direttiva 2014/53/UE	Norme
Articolo 3.1a (Sicurezza)	EN 60601-1 EN 50364
Articolo 3.1b (Compatibilità elettromagnetica)	EN 60601-1-2 EN 301 489-1 EN 301 489-3
Articolo 3.2 (Spettro)	EN 300 330

Dan O'Callaghan

Nome, VP, Affari regolatori e Qualità

27/July/2022

[Publish Date]

Data

Data di entrata in vigore della
dichiarazione

Dudi Reznick

Nome, VP, Ricerca e Sviluppo

28/July/2022

[Publish Date]

Data

Data di entrata in vigore della
dichiarazione



Numero di catalogo	Nome del prodotto	Tipo di dispositivo
GA-1000000	AcuPulse DUO	System
GA-1000000CN	AcuPulse DUO CHINA	System
RG-1000000	Refurbish AcuPulse DUO	System
GA-2000000	UltraPulse DUO	System
RG-2000000	Refurbished UltraPulse DUO	System
GA-2006098	Lumenis Pulse 30H with cart	System
GA-2003322	Lumenis Pulse 30H, with cart Japan	System
RG -2006098	Lumenis Pulse 30H with cart, refurbished	System
GA-1008943	Lumenis Pulse 50H, INT	System
GA-1008946	Lumenis Pulse 50H, DOM	System
GA-1008943CN	Lumenis Pulse 50H, China	System
GA-2006378	Lumenis Pulse 60H, 50Hz	System
GA-2006379	Lumenis Pulse 60H, 60Hz	System
GA-1008942	Lumenis Pulse 100H INT	System
GA-1008944	Lumenis Pulse 100H DOM	System
RG-1008944	Lumenis Pulse 100H, INT, Refurbished	System
RG-1008942	Lumenis Pulse 100H, DOM, Refurbished	System
GA-1008942CN	Lumenis Pulse 100H, China	System



CE-Conformiteitsverklaring

Richtlijn 2014/53/EU
DoC-1016493

Lumenis Ltd.
Yokneam Industrial Park
Hakidma Street 6,
Yokneam 2069204, Israel

Wij verklaren op onze eigen verantwoording dat de volgende modellen van radioapparatuur in overeenstemming zijn met de relevante harmonisatiewetgeving van de Gemeenschap in Richtlijn 2014/53/EU:

AcuPulse DUO (LT-LFS03-SYS-02)
UltraPulse DUO (LT-LFS03-SYS-02)
Lumenis Pulse 100H/50H (LT-LFS03-SYS-06A, LT-LFS03-SYS-06R)
Lumenis Pulse 60H (LT-LFS03-SYS-07)
Lumenis Pulse 30H (LT-LFS03-SYS-09)

De relevante geharmoniseerde normen en/of technische specificaties die zijn toegepast in verband met deze conformiteitsverklaring zijn:

Richtlijn 2014/53/EU	Normen
Artikel 3.1a (Veiligheid)	EN 60601-1 EN 50364
Artikel 3.1b (Elektromagnetische compatibiliteit)	EN 60601-1-2 EN 301 489-1 EN 301 489-3
Artikel 3.2 (Spectrum)	EN 300 330

Dan O'Callaghan

Naam, VP, Regelgevende Zaken en Kwaliteit

27/July/2022

[Publish Date]

Datum

Dudi Herzick

Naam, VP, Onderzoek & Ontwikkeling

Geldigheidsdatum verklaring

28/July/2022

[Publish Date]

Datum

Geldigheidsdatum verklaring



Catalogus-nummer	Productnaam	Type Hulpmiddel
GA-1000000	AcuPulse DUO	System
GA-1000000CN	AcuPulse DUO CHINA	System
RG-1000000	Refurbish AcuPulse DUO	System
GA-2000000	UltraPulse DUO	System
RG-2000000	Refurbished UltraPulse DUO	System
GA-2006098	Lumenis Pulse 30H with cart	System
GA-2003322	Lumenis Pulse 30H, with cart Japan	System
RG -2006098	Lumenis Pulse 30H with cart, refurbished	System
GA-1008943	Lumenis Pulse 50H, INT	System
GA-1008946	Lumenis Pulse 50H, DOM	System
GA-1008943CN	Lumenis Pulse 50H, China	System
GA-2006378	Lumenis Pulse 60H, 50Hz	System
GA-2006379	Lumenis Pulse 60H, 60Hz	System
GA-1008942	Lumenis Pulse 100H INT	System
GA-1008944	Lumenis Pulse 100H DOM	System
RG-1008944	Lumenis Pulse 100H, INT, Refurbished	System
RG-1008942	Lumenis Pulse 100H, DOM, Refurbished	System
GA-1008942CN	Lumenis Pulse 100H, China	System



Declaração de Conformidade

Diretiva 2014/53/UE
DoC-1016493

Lumenis Ltd.
Yokneam Industrial Park
Hakidma Street 6,
Yokneam 2069204, Israel

Declaramos sob nossa única responsabilidade que os seguintes modelos de equipamentos de rádio e acessórios estão em conformidade com a legislação de harmonização relevante da União Europeia na Diretiva 2014/53/UE:

AcuPulse DUO (LT-LFS03-SYS-02)
UltraPulse DUO (LT-LFS03-SYS-02)
Lumenis Pulse 100H/50H (LT-LFS03-SYS-06A, LT-LFS03-SYS-06R)
Lumenis Pulse 60H (LT-LFS03-SYS-07)
Lumenis Pulse 30H (LT-LFS03-SYS-09)

As normas harmonizadas relevantes e/ou as especificações técnicas que foram aplicadas relativamente a esta declaração de conformidade são:

Diretiva 2014/53/UE	Normas
Artigo n.º 3.1a (Segurança)	EN 60601-1 EN 50364
Artigo n.º 3.1b (Compatibilidade eletromagnética)	EN 60601-1-2 EN 301 489-1 EN 301 489-3
Artigo n.º 3.2 (Espectro)	EN 300 330

Dan O'Callaghan
Nome, VP, Assuntos Regulamentares e
Qualidade

27/July/2022
[Publish Date]
Data

Ovid Reznick
Nome, VP, Investigação e Desenvolvimento

Data de validade da declaração
28/July/2022
[Publish Date]
Data

Data de validade da declaração



Referência	Nome do produto	Tipo de dispositivo
GA-1000000	AcuPulse DUO	System
GA-1000000CN	AcuPulse DUO CHINA	System
RG-1000000	Refurbish AcuPulse DUO	System
GA-2000000	UltraPulse DUO	System
RG-2000000	Refurbished UltraPulse DUO	System
GA-2006098	Lumenis Pulse 30H with cart	System
GA-2003322	Lumenis Pulse 30H, with cart Japan	System
RG -2006098	Lumenis Pulse 30H with cart, refurbished	System
GA-1008943	Lumenis Pulse 50H, INT	System
GA-1008946	Lumenis Pulse 50H, DOM	System
GA-1008943CN	Lumenis Pulse 50H, China	System
GA-2006378	Lumenis Pulse 60H, 50Hz	System
GA-2006379	Lumenis Pulse 60H, 60Hz	System
GA-1008942	Lumenis Pulse 100H INT	System
GA-1008944	Lumenis Pulse 100H DOM	System
RG-1008944	Lumenis Pulse 100H, INT, Refurbished	System
RG-1008942	Lumenis Pulse 100H, DOM, Refurbished	System
GA-1008942CN	Lumenis Pulse 100H, China	System



ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ

Οδηγία 2014/53/EE

DoC-1016493

Lumenis Ltd.
Yokneam Industrial Park
Hakidma Street 6,
Yokneam 2069204, Israel

Δηλώνουμε με αποκλειστική μας ευθύνη ότι τα παρακάτω μοντέλα ραδιοεξοπλισμού είναι σε συμμόρφωση με τη σχετική ενωσιακή νομοθεσία εναρμόνισης που ορίζεται στην Οδηγία 2014/53/EE:

AcuPulse DUO (LT-LFS03-SYS-02)
UltraPulse DUO (LT-LFS03-SYS-02)
Lumenis Pulse 100H/50H (LT-LFS03-SYS-06A, LT-LFS03-SYS-06R)
Lumenis Pulse 60H (LT-LFS03-SYS-07)
Lumenis Pulse 30H (LT-LFS03-SYS-09)

Τα σχετικά εναρμονισμένα πρότυπα ή/και οι τεχνικές προδιαγραφές που έχουν εφαρμοστεί σε σχέση με την παρούσα δήλωση συμμόρφωσης είναι:

Οδηγία 2014/53/EE	Πρότυπα
Άρθρο 3.1a (Ασφάλεια)	EN 60601-1 EN 50364
Άρθρο 3.1b (Ηλεκτρομαγνητική συμβατότητα)	EN 60601-1-2 EN 301 489-1 EN 301 489-3
Άρθρο 3.2 (Φάσμα)	EN 300 330

Dan O Callaghan

Όνομα, Αντιπρόεδρος, Κανονιστικές Υποθέσεις
και Ποιότητα

27/July/2022

[Publish Date]

Ημερομηνία

Ημερομηνία ισχύος δήλωσης

Rudi Reznick

Όνομα, Αντιπρόεδρος, Έρευνα και Ανάπτυξη

28/July/2022

[Publish Date]

Ημερομηνία

Ημερομηνία ισχύος δήλωσης



Αριθμός καταλόγου	Όνομα προϊόντος	Τύπος συσκευής
GA-1000000	AcuPulse DUO	System
GA-1000000CN	AcuPulse DUO CHINA	System
RG-1000000	Refurbish AcuPulse DUO	System
GA-2000000	UltraPulse DUO	System
RG-2000000	Refurbished UltraPulse DUO	System
GA-2006098	Lumenis Pulse 30H with cart	System
GA-2003322	Lumenis Pulse 30H, with cart Japan	System
RG -2006098	Lumenis Pulse 30H with cart, refurbished	System
GA-1008943	Lumenis Pulse 50H, INT	System
GA-1008946	Lumenis Pulse 50H, DOM	System
GA-1008943CN	Lumenis Pulse 50H, China	System
GA-2006378	Lumenis Pulse 60H, 50Hz	System
GA-2006379	Lumenis Pulse 60H, 60Hz	System
GA-1008942	Lumenis Pulse 100H INT	System
GA-1008944	Lumenis Pulse 100H DOM	System
RG-1008944	Lumenis Pulse 100H, INT, Refurbished	System
RG-1008942	Lumenis Pulse 100H, DOM, Refurbished	System
GA-1008942CN	Lumenis Pulse 100H, China	System



Samsvarserklæring

Direktiv 2014/53/EU
DoC-1016493

Lumenis Ltd.
Yokneam Industrial Park
Hakidma Street 6,
Yokneam 2069204, Israel

Vi erklærer herved på eget ansvar at følgende radioutstyrsmodeller er i samsvar med den relevante harmoniseringslovgivningen i direktiv 2014/53/EU:

AcuPulse DUO (LT-LFS03-SYS-02)
UltraPulse DUO (LT-LFS03-SYS-02)
Lumenis Pulse 100H/50H (LT-LFS03-SYS-06A, LT-LFS03-SYS-06R)
Lumenis Pulse 60H (LT-LFS03-SYS-07)
Lumenis Pulse 30H (LT-LFS03-SYS-09)

De relevante harmoniserte standardene og/eller tekniske spesifikasjonene som er brukt i forbindelse med denne samsvarserklæringen, er:

Direktiv 2014/53/EU	Standardene
Artikkel 3.1a (Sikkerhet)	EN 60601-1 EN 50364
Artikkel 3.1b (Elektromagnetisk kompatibilitet)	EN 60601-1-2 EN 301 489-1 EN 301 489-3
Artikkel 3.2 (Spektrum)	EN 300 330

Dan O'Callaghan

Navn, VP, regulatoriske forhold og kvalitet

27/July/2022
[Publish Date]

Dato

Gyldighetsdato for erklæring

Dudi Dornick

Navn, VP, forskning og utvikling

28/July/2022
[Publish Date]

Dato

Gyldighetsdato for erklæring



Katalognummer	Produktnavn	Enhetsstype
GA-1000000	AcuPulse DUO	System
GA-1000000CN	AcuPulse DUO CHINA	System
RG-1000000	Refurbish AcuPulse DUO	System
GA-2000000	UltraPulse DUO	System
RG-2000000	Refurbished UltraPulse DUO	System
GA-2006098	Lumenis Pulse 30H with cart	System
GA-2003322	Lumenis Pulse 30H, with cart Japan	System
RG -2006098	Lumenis Pulse 30H with cart, refurbished	System
GA-1008943	Lumenis Pulse 50H, INT	System
GA-1008946	Lumenis Pulse 50H, DOM	System
GA-1008943CN	Lumenis Pulse 50H, China	System
GA-2006378	Lumenis Pulse 60H, 50Hz	System
GA-2006379	Lumenis Pulse 60H, 60Hz	System
GA-1008942	Lumenis Pulse 100H INT	System
GA-1008944	Lumenis Pulse 100H DOM	System
RG-1008944	Lumenis Pulse 100H, INT, Refurbished	System
RG-1008942	Lumenis Pulse 100H, DOM, Refurbished	System
GA-1008942CN	Lumenis Pulse 100H, China	System



Overensstemmelseserklæring

Direktiv 2014/53/EU

DoC-1016493

Lumenis Ltd.
Yokneam Industrial Park
Hakidma Street 6,
Yokneam 2069204, Israel

Vi erklærer hermed som eneansvarlige, at følgende radioudstyrsmødelles er i overensstemmelse med de relevante unionsharmoniseringsbestemmelser i direktiv 2014/53/EU:

AcuPulse DUO (LT-LFS03-SYS-02)
UltraPulse DUO (LT-LFS03-SYS-02)
Lumenis Pulse 100H/50H (LT-LFS03-SYS-06A, LT-LFS03-SYS-06R)
Lumenis Pulse 60H (LT-LFS03-SYS-07)
Lumenis Pulse 30H (LT-LFS03-SYS-09)

De relevante harmoniserede standarder og/eller tekniske specifikationer, der er anvendt i relation til denne overensstemmelseserklæring, er:

Direktiv 2014/53/EU	Standarder
Artikel 3.1a (Sikkerhed)	EN 60601-1 EN 50364
Artikel 3.1b (Elektromagnetisk kompatibilitet)	EN 60601-1-2 EN 301 489-1 EN 301 489-3
Artikel 3.2 (Spektrum)	EN 300 330

Dan O'Callaghan
Navn, vicedirektør, retsforskrifter og kvalitet

27/July/2022
[Publish Date]
Dato

Dudi Benicov
Navn, vicedirektør, forskning og udvikling

Erklæringens ikrafttrædelsesdato
28/July/2022
[Publish Date]
Dato

Erklæringens ikrafttrædelsesdato



Katalognummer	Produktnavn	Enhedstype
GA-1000000	AcuPulse DUO	System
GA-1000000CN	AcuPulse DUO CHINA	System
RG-1000000	Refurbish AcuPulse DUO	System
GA-2000000	UltraPulse DUO	System
RG-2000000	Refurbished UltraPulse DUO	System
GA-2006098	Lumenis Pulse 30H with cart	System
GA-2003322	Lumenis Pulse 30H, with cart Japan	System
RG -2006098	Lumenis Pulse 30H with cart, refurbished	System
GA-1008943	Lumenis Pulse 50H, INT	System
GA-1008946	Lumenis Pulse 50H, DOM	System
GA-1008943CN	Lumenis Pulse 50H, China	System
GA-2006378	Lumenis Pulse 60H, 50Hz	System
GA-2006379	Lumenis Pulse 60H, 60Hz	System
GA-1008942	Lumenis Pulse 100H INT	System
GA-1008944	Lumenis Pulse 100H DOM	System
RG-1008944	Lumenis Pulse 100H, INT, Refurbished	System
RG-1008942	Lumenis Pulse 100H, DOM, Refurbished	System
GA-1008942CN	Lumenis Pulse 100H, China	System



Försäkran om överensstämmelse

Direktiv 2014/53/EU

DoC-1016493

Lumenis Ltd.
Yokneam Industrial Park
Hakidma Street 6,
Yokneam 2069204, Israel

Vi försäkrar under eget ansvar att följande radioutrustningsmodeller överensstämmer med den relevanta unionslagstiftningen om harmonisering i direktiv 2014/53/EU:

AcuPulse DUO (LT-LFS03-SYS-02)
UltraPulse DUO (LT-LFS03-SYS-02)
Lumenis Pulse 100H/50H (LT-LFS03-SYS-06A, LT-LFS03-SYS-06R)
Lumenis Pulse 60H (LT-LFS03-SYS-07)
Lumenis Pulse 30H (LT-LFS03-SYS-09)

De relevanta harmoniserade standarderna och/eller tekniska specifikationer som har tillämpats i samband med denna försäkran om överensstämmelse är:

Direktiv 2014/53/EU	Standarderna
Artikel 3.1a (Säkerhet)	EN 60601-1 EN 50364
Artikel 3.1b (Elektromagnetisk kompatibilitet)	EN 60601-1-2 EN 301 489-1 EN 301 489-3
Artikel 3.2 (Spektrum)	EN 300 330

Don O'Callaghan

Namn, VP för regleringsfrågor och kvalitet

27/July/2022

[Publish Date]

Datum

Giltighetsdatum för försäkran

Dudi Reznick

Namn, VP för forskning och utveckling

28/July/2022

[Publish Date]

Datum

Giltighetsdatum för försäkran



Katalognummer	Produktnamn	Enhetstyp
GA-1000000	AcuPulse DUO	System
GA-1000000CN	AcuPulse DUO CHINA	System
RG-1000000	Refurbish AcuPulse DUO	System
GA-2000000	UltraPulse DUO	System
RG-2000000	Refurbished UltraPulse DUO	System
GA-2006098	Lumenis Pulse 30H with cart	System
GA-2003322	Lumenis Pulse 30H, with cart Japan	System
RG -2006098	Lumenis Pulse 30H with cart, refurbished	System
GA-1008943	Lumenis Pulse 50H, INT	System
GA-1008946	Lumenis Pulse 50H, DOM	System
GA-1008943CN	Lumenis Pulse 50H, China	System
GA-2006378	Lumenis Pulse 60H, 50Hz	System
GA-2006379	Lumenis Pulse 60H, 60Hz	System
GA-1008942	Lumenis Pulse 100H INT	System
GA-1008944	Lumenis Pulse 100H DOM	System
RG-1008944	Lumenis Pulse 100H, INT, Refurbished	System
RG-1008942	Lumenis Pulse 100H, DOM, Refurbished	System
GA-1008942CN	Lumenis Pulse 100H, China	System



Vyhlásenie o Zhode

Smernica 2014/53/EÚ

DoC-1016493

Lumenis Ltd.
Yokneam Industrial Park
Hakidma Street 6,
Yokneam 2069204, Israel

Vyhlasujeme na svoju vlastnú zodpovednosť, že nasledujúce modely rádiových zariadení sú v súlade s príslušnými harmonizačnými právnymi predpismi Únie v smernici 2014/53/EÚ:

AcuPulse DUO (LT-LFS03-SYS-02)
UltraPulse DUO (LT-LFS03-SYS-02)
Lumenis Pulse 100H/50H (LT-LFS03-SYS-06A, LT-LFS03-SYS-06R)
Lumenis Pulse 60H (LT-LFS03-SYS-07)
Lumenis Pulse 30H (LT-LFS03-SYS-09)

Príslušné harmonizované normy a/alebo technické špecifikácie, ktoré sa použili v súvislosti s týmto vyhlásením o zhode, sú:

Smernica 2014/53/EÚ	Normy
Článku 3.1a (Bezpečnosť)	EN 60601-1 EN 50364
Článku 3.1b (Elektromagnetická kompatibilita)	EN 60601-1-2 EN 301 489-1 EN 301 489-3
Článku 3.2 (Spektrum)	EN 300 330

Dan O'Callaghan

Meno, VP, regulačné záležitosti a kvalita

27/July/2022

[Publish Date]

Dátum

Dátum platnosti vyhlásenia

Avdi Beznichev

Meno, VP, výskum a vývoj

28/July/2022

[Publish Date]

Dátum

Dátum platnosti vyhlásenia



Katalógové číslo	Názov produktu	Typ pomôcky
GA-1000000	AcuPulse DUO	System
GA-1000000CN	AcuPulse DUO CHINA	System
RG-1000000	Refurbish AcuPulse DUO	System
GA-2000000	UltraPulse DUO	System
RG-2000000	Refurbished UltraPulse DUO	System
GA-2006098	Lumenis Pulse 30H with cart	System
GA-2003322	Lumenis Pulse 30H, with cart Japan	System
RG -2006098	Lumenis Pulse 30H with cart, refurbished	System
GA-1008943	Lumenis Pulse 50H, INT	System
GA-1008946	Lumenis Pulse 50H, DOM	System
GA-1008943CN	Lumenis Pulse 50H, China	System
GA-2006378	Lumenis Pulse 60H, 50Hz	System
GA-2006379	Lumenis Pulse 60H, 60Hz	System
GA-1008942	Lumenis Pulse 100H INT	System
GA-1008944	Lumenis Pulse 100H DOM	System
RG-1008944	Lumenis Pulse 100H, INT, Refurbished	System
RG-1008942	Lumenis Pulse 100H, DOM, Refurbished	System
GA-1008942CN	Lumenis Pulse 100H, China	System



Prohlášení o Shodě

Směrnice 2014/53/EU
DoC-1016493

Lumenis Ltd.
Yokneam Industrial Park
Hakidma Street 6,
Yokneam 2069204, Israel

Na vlastní odpovědnost prohlašujeme, že následující model(y) radiofrekvenčních zařízení jsou v souladu s příslušnými harmonizačními právními předpisy Unie, jak uvádí Směrnice 2014/53/EU:

AcuPulse DUO (LT-LFS03-SYS-02)
UltraPulse DUO (LT-LFS03-SYS-02)
Lumenis Pulse 100H/50H (LT-LFS03-SYS-06A, LT-LFS03-SYS-06R)
Lumenis Pulse 60H (LT-LFS03-SYS-07)
Lumenis Pulse 30H (LT-LFS03-SYS-09)

Příslušné harmonizované normy a/nebo technické požadavky, které byly použity v souvislosti s tímto prohlášením o shodě, jsou:

Směrnice 2014/53/EU	Normy
Článku 3.1a (Bezpečnost)	EN 60601-1 EN 50364
Článku 3.1b (Elektromagnetická kompatibilita)	EN 60601-1-2 EN 301 489-1 EN 301 489-3
Článku 3.2 (Spektrum)	EN 300 330

Deir O' Callaghan
Jméno, VP, Regulační záležitosti a kvalita

27/July/2022
[Publish Date]
Datum

Dudi Reznick
Jméno, VP, Výzkum a vývoj

Datum platnosti prohlášení
28/July/2022
[Publish Date]
Datum

Datum platnosti prohlášení



Katalogové číslo	Název produktu	Typ zařízení
GA-1000000	AcuPulse DUO	System
GA-1000000CN	AcuPulse DUO CHINA	System
RG-1000000	Refurbish AcuPulse DUO	System
GA-2000000	UltraPulse DUO	System
RG-2000000	Refurbished UltraPulse DUO	System
GA-2006098	Lumenis Pulse 30H with cart	System
GA-2003322	Lumenis Pulse 30H, with cart Japan	System
RG -2006098	Lumenis Pulse 30H with cart, refurbished	System
GA-1008943	Lumenis Pulse 50H, INT	System
GA-1008946	Lumenis Pulse 50H, DOM	System
GA-1008943CN	Lumenis Pulse 50H, China	System
GA-2006378	Lumenis Pulse 60H, 50Hz	System
GA-2006379	Lumenis Pulse 60H, 60Hz	System
GA-1008942	Lumenis Pulse 100H INT	System
GA-1008944	Lumenis Pulse 100H DOM	System
RG-1008944	Lumenis Pulse 100H, INT, Refurbished	System
RG-1008942	Lumenis Pulse 100H, DOM, Refurbished	System
GA-1008942CN	Lumenis Pulse 100H, China	System



Megfelelőségi nyilatkozat

2014/53/EU irányelv
DoC-1016493

Lumenis Ltd.
Yokneam Industrial Park
Hakidma Street 6,
Yokneam 2069204, Israel

Teljes felelősséggel kijelentjük, hogy az itt felsorolt rádiókészülékek megfelelnek a rájuk vonatkozó, a 2014/53/EU irányelvben rögzített Uniós harmonizációs jogszabályoknak:

AcuPulse DUO (LT-LFS03-SYS-02)
UltraPulse DUO (LT-LFS03-SYS-02)
Lumenis Pulse 100H/50H (LT-LFS03-SYS-06A, LT-LFS03-SYS-06R)
Lumenis Pulse 60H (LT-LFS03-SYS-07)
Lumenis Pulse 30H (LT-LFS03-SYS-09)

A jelen megfelelőség nyilatkozat vonatkozásában alkalmazott megfelelő harmonizált szabványok és/vagy műszaki előírások a következők:

2014/53/EU irányelv	Szabványok
3.(1) a) cikk (Biztonság)	EN 60601-1 EN 50364
3.(1) b) cikk (Elektromágneses kompatibilitás)	EN 60601-1-2 EN 301 489-1 EN 301 489-3
3.(2) cikk (Spektrum)	EN 300 330

David O'Callaghan
Név, ügyv. ig., Szabályozói ügyek és
Minőségellenőrzés

27/July/2022
[Publish Date]
Dátum

Avdi Reznick
Név, ügyv. ig., Kutatás, fejlesztés

Nyilatkozat érvényességi dátuma
28/July/2022
[Publish Date]
Dátum

Nyilatkozat érvényességi dátuma



Katalógusszám	Terméknév	Eszköztípus
GA-1000000	AcuPulse DUO	System
GA-1000000CN	AcuPulse DUO CHINA	System
RG-1000000	Refurbish AcuPulse DUO	System
GA-2000000	UltraPulse DUO	System
RG-2000000	Refurbished UltraPulse DUO	System
GA-2006098	Lumenis Pulse 30H with cart	System
GA-2003322	Lumenis Pulse 30H, with cart Japan	System
RG -2006098	Lumenis Pulse 30H with cart, refurbished	System
GA-1008943	Lumenis Pulse 50H, INT	System
GA-1008946	Lumenis Pulse 50H, DOM	System
GA-1008943CN	Lumenis Pulse 50H, China	System
GA-2006378	Lumenis Pulse 60H, 50Hz	System
GA-2006379	Lumenis Pulse 60H, 60Hz	System
GA-1008942	Lumenis Pulse 100H INT	System
GA-1008944	Lumenis Pulse 100H DOM	System
RG-1008944	Lumenis Pulse 100H, INT, Refurbished	System
RG-1008942	Lumenis Pulse 100H, DOM, Refurbished	System
GA-1008942CN	Lumenis Pulse 100H, China	System



Vaatimustenmukaisuusvakuutus

Direktiivi 2014/53/EU

DoC-1016493

Lumenis Ltd.

Yokneam Industrial Park

Hakidma Street 6,

Yokneam 2069204, Israel

Vakuutamme omalla vastuullamme, että seuraavat radiolaitemallit ovat direktiivin 2014/53/EU asiaankuuluvan unionin harmonisointilainsäädännön mukaisia:

AcuPulse DUO (LT-LFS03-SYS-02)

UltraPulse DUO (LT-LFS03-SYS-02)

Lumenis Pulse 100H/50H (LT-LFS03-SYS-06A, LT-LFS03-SYS-06R)

Lumenis Pulse 60H (LT-LFS03-SYS-07)

Lumenis Pulse 30H (LT-LFS03-SYS-09)

Asiaankuuluvat yhdenmukaistetut standardit ja/tai tekniset eritelvät, joita on sovellettu tähän vaatimustenmukaisuusvakuutukseen, ovat:

Direktiivi 2014/53/EU	Standardit
Artikla 3.1a (Turvallisuus)	EN 60601-1 EN 50364
Artikla 3.1b (Elektromagneettinen yhteensopivuus)	EN 60601-1-2 EN 301 489-1 EN 301 489-3
Artikla 3.2 (Spektri)	EN 300 330

Don O'Callaghan

Nimi, VP, sääntelyasiat ja laatu

27/July/2022

[Publish Date]

Päivämäärä

Dudi Reznick

Nimi, VP, tutkimus ja kehitys

Vakuutuksen voimaantulopäivä

- 28/July/2022

[Publish Date]

Päivämäärä

Vakuutuksen voimaantulopäivä



Luettelonumero	Tuotteen nimi	Laitteen tyyppi
GA-1000000	AcuPulse DUO	System
GA-1000000CN	AcuPulse DUO CHINA	System
RG-1000000	Refurbish AcuPulse DUO	System
GA-2000000	UltraPulse DUO	System
RG-2000000	Refurbished UltraPulse DUO	System
GA-2006098	Lumenis Pulse 30H with cart	System
GA-2003322	Lumenis Pulse 30H, with cart Japan	System
RG -2006098	Lumenis Pulse 30H with cart, refurbished	System
GA-1008943	Lumenis Pulse 50H, INT	System
GA-1008946	Lumenis Pulse 50H, DOM	System
GA-1008943CN	Lumenis Pulse 50H, China	System
GA-2006378	Lumenis Pulse 60H, 50Hz	System
GA-2006379	Lumenis Pulse 60H, 60Hz	System
GA-1008942	Lumenis Pulse 100H INT	System
GA-1008944	Lumenis Pulse 100H DOM	System
RG-1008944	Lumenis Pulse 100H, INT, Refurbished	System
RG-1008942	Lumenis Pulse 100H, DOM, Refurbished	System
GA-1008942CN	Lumenis Pulse 100H, China	System



Deklaracja zgodności

Dyrektywa 2014/53/UE

DoC-1016493

Lumenis Ltd.
Yokneam Industrial Park
Hakidma Street 6,
Yokneam 2069204, Israel

Deklarujemy na naszą wyłączną odpowiedzialność, że następujące modele urządzeń radiowych są zgodne z odpowiednimi unijnymi przepisami harmonizacyjnymi dotyczącymi dyrektywy 2014/53/UE:

AcuPulse DUO (LT-LFS03-SYS-02)
UltraPulse DUO (LT-LFS03-SYS-02)
Lumenis Pulse 100H/50H (LT-LFS03-SYS-06A, LT-LFS03-SYS-06R)
Lumenis Pulse 60H (LT-LFS03-SYS-07)
Lumenis Pulse 30H (LT-LFS03-SYS-09)

Odpowiednie normy zharmonizowane i/lub specyfikacje techniczne zastosowane w związku z niniejszą deklaracją zgodności to:

Dyrektywa 2014/53/UE	Normy
Artykuł 3.1a (Bezpieczeństwo)	EN 60601-1 EN 50364
Artykuł 3.1b (Kompatybilność elektromagnetyczna)	EN 60601-1-2 EN 301 489-1 EN 301 489-3
Artykuł 3.2 (Widmo)	EN 300 330

Dan O'Callaghan

Imię i nazwisko wiceprezesa ds. regulacyjnych
i kontroli jakości

27 July 2022

[Publish Date]

Data

Data ważności deklaracji

Dudi Reznick

Imię i nazwisko wiceprezesa ds. badań
i rozwoju

28 July 2022

[Publish Date]

Data

Data ważności deklaracji



Numer katalogowy	Nazwa produktu	Rodzaj urządzenia
GA-1000000	AcuPulse DUO	System
GA-1000000CN	AcuPulse DUO CHINA	System
RG-1000000	Refurbish AcuPulse DUO	System
GA-2000000	UltraPulse DUO	System
RG-2000000	Refurbished UltraPulse DUO	System
GA-2006098	Lumenis Pulse 30H with cart	System
GA-2003322	Lumenis Pulse 30H, with cart Japan	System
RG -2006098	Lumenis Pulse 30H with cart, refurbished	System
GA-1008943	Lumenis Pulse 50H, INT	System
GA-1008946	Lumenis Pulse 50H, DOM	System
GA-1008943CN	Lumenis Pulse 50H, China	System
GA-2006378	Lumenis Pulse 60H, 50Hz	System
GA-2006379	Lumenis Pulse 60H, 60Hz	System
GA-1008942	Lumenis Pulse 100H INT	System
GA-1008944	Lumenis Pulse 100H DOM	System
RG-1008944	Lumenis Pulse 100H, INT, Refurbished	System
RG-1008942	Lumenis Pulse 100H, DOM, Refurbished	System
GA-1008942CN	Lumenis Pulse 100H, China	System



Декларация за съответствие

Директива 2014/53/EC

DoC-1016493

Lumenis Ltd.
Yokneam Industrial Park
Hakidma Street 6,
Yokneam 2069204, Israel

Ние декларираме на наша лична отговорност, че следните модели радиооборудване отговарят на съответното законодателство на Съюза за хармонизация, предвиждащо Директива 2014/53/EC:

AcuPulse DUO (LT-LFS03-SYS-02)
UltraPulse DUO (LT-LFS03-SYS-02)
Lumenis Pulse 100H/50H (LT-LFS03-SYS-06A, LT-LFS03-SYS-06R)
Lumenis Pulse 60H (LT-LFS03-SYS-07)
Lumenis Pulse 30H (LT-LFS03-SYS-09)

Съответните хармонизирани стандарти и/или технически спецификации, прилагани във връзка с тази декларация за съответствие, са:

Директива 2014/53/EC	Стандарти
Член 3.1a (Безопасност)	EN 60601-1 EN 50364
Член 3.1b (Електромагнитна съвместимост)	EN 60601-1-2 EN 301 489-1 EN 301 489-3
Член 3.2 (Спектър)	EN 300 330

Dan O'Callaghan

Име, Вицепрезидент по регулаторни дейности и качество

27/July/2022

[Publish Date]

Дата

Дата на валидност на декларацията

Dudi Reznick

Име, Вицепрезидент по изследователски дейности и разработка

28/July/2022

[Publish Date]

Дата

Дата на валидност на декларацията



Каталожен номер	Название на продукта	Вид на устройството
GA-1000000	AcuPulse DUO	System
GA-1000000CN	AcuPulse DUO CHINA	System
RG-1000000	Refurbish AcuPulse DUO	System
GA-2000000	UltraPulse DUO	System
RG-2000000	Refurbished UltraPulse DUO	System
GA-2006098	Lumenis Pulse 30H with cart	System
GA-2003322	Lumenis Pulse 30H, with cart Japan	System
RG -2006098	Lumenis Pulse 30H with cart, refurbished	System
GA-1008943	Lumenis Pulse 50H, INT	System
GA-1008946	Lumenis Pulse 50H, DOM	System
GA-1008943CN	Lumenis Pulse 50H, China	System
GA-2006378	Lumenis Pulse 60H, 50Hz	System
GA-2006379	Lumenis Pulse 60H, 60Hz	System
GA-1008942	Lumenis Pulse 100H INT	System
GA-1008944	Lumenis Pulse 100H DOM	System
RG-1008944	Lumenis Pulse 100H, INT, Refurbished	System
RG-1008942	Lumenis Pulse 100H, DOM, Refurbished	System
GA-1008942CN	Lumenis Pulse 100H, China	System



Izjava o sukladnosti

Direktiva 2014/53/EU
DoC-1016493

Lumenis Ltd.
Yokneam Industrial Park
Hakidma Street 6,
Yokneam 2069204, Israel

Izjavljujemo na našu isključivu odgovornost da su sljedeći modeli radijske opreme u skladu s relevantnim zakonodavstvom Unije o usklađivanju koje predviđa Direktiva 2014/53/EU:

AcuPulse DUO (LT-LFS03-SYS-02)
UltraPulse DUO (LT-LFS03-SYS-02)
Lumenis Pulse 100H/50H (LT-LFS03-SYS-06A, LT-LFS03-SYS-06R)
Lumenis Pulse 60H (LT-LFS03-SYS-07)
Lumenis Pulse 30H (LT-LFS03-SYS-09)

Relevantni usklađeni standardi i/ili tehničke specifikacije primijenjene u vezi s ovom izjavom o sukladnosti su:

Direktiva 2014/53/EU	Standardi
Članak 3.1a (Sigurnost)	EN 60601-1 EN 50364
Članak 3.1b (Elektromagnetska kompatibilnost)	EN 60601-1-2 EN 301 489-1 EN 301 489-3
Članak 3.2 (Spektar)	EN 300 330

Dan O'Callaghan
Ime i prezime, potpredsjednik, Regulatorni poslovi i kvaliteta

27/July/2022
[Publish Date]
Datum

Dudi Reznick
Ime i prezime, potpredsjednik, Istraživanje i razvoj

28/July/2022
[Publish Date]
Datum

Datum valjanosti izjave

Datum valjanosti izjave



Kataloški broj (HR)	Naziv proizvoda (HR)	Vrsta uređaja (HR)
GA-1000000	AcuPulse DUO	System
GA-1000000CN	AcuPulse DUO CHINA	System
RG-1000000	Refurbish AcuPulse DUO	System
GA-2000000	UltraPulse DUO	System
RG-2000000	Refurbished UltraPulse DUO	System
GA-2006098	Lumenis Pulse 30H with cart	System
GA-2003322	Lumenis Pulse 30H, with cart Japan	System
RG -2006098	Lumenis Pulse 30H with cart, refurbished	System
GA-1008943	Lumenis Pulse 50H, INT	System
GA-1008946	Lumenis Pulse 50H, DOM	System
GA-1008943CN	Lumenis Pulse 50H, China	System
GA-2006378	Lumenis Pulse 60H, 50Hz	System
GA-2006379	Lumenis Pulse 60H, 60Hz	System
GA-1008942	Lumenis Pulse 100H INT	System
GA-1008944	Lumenis Pulse 100H DOM	System
RG-1008944	Lumenis Pulse 100H, INT, Refurbished	System
RG-1008942	Lumenis Pulse 100H, DOM, Refurbished	System
GA-1008942CN	Lumenis Pulse 100H, China	System



Declarație de Conformitate

Directiva 2014/53/UE
DoC-1016493

Lumenis Ltd.
Yokneam Industrial Park
Hakidma Street 6,
Yokneam 2069204, Israel

Declarăm pe propria noastră responsabilitate că următoarele modele de echipamente radio sunt conforme cu legislația de armonizare a Uniunii relevante care prevede Directiva 2014/53/UE:

AcuPulse DUO (LT-LFS03-SYS-02)
UltraPulse DUO (LT-LFS03-SYS-02)
Lumenis Pulse 100H/50H (LT-LFS03-SYS-06A, LT-LFS03-SYS-06R)
Lumenis Pulse 60H (LT-LFS03-SYS-07)
Lumenis Pulse 30H (LT-LFS03-SYS-09)

Standardele și/sau specificațiile tehnice armonizate relevante aplicate în legătură cu această declarație de conformitate sunt:

Directiva 2014/53/UE	Standardele
Articol 3.1a (Siguranță)	EN 60601-1 EN 50364
Articol 3.1b (Compatibilitate electromagnetică)	EN 60601-1-2 EN 301 489-1 EN 301 489-3
Articol 3.2 (Spectru)	EN 300 330

Dan O'Callaghan
Nume, VP, Afaceri de reglementare și Calitate

27/July/2022
[Publish Date]
Data

Dedi Reznicki
Nume, VP, Cercetare și Dezvoltare

Data de valabilitate a declarației
28/July/2022
[Publish Date]
Data

Data de valabilitate a declarației



Număr de catalog	Denumire produs	Tipul dispozitivului
GA-1000000	AcuPulse DUO	System
GA-1000000CN	AcuPulse DUO CHINA	System
RG-1000000	Refurbish AcuPulse DUO	System
GA-2000000	UltraPulse DUO	System
RG-2000000	Refurbished UltraPulse DUO	System
GA-2006098	Lumenis Pulse 30H with cart	System
GA-2003322	Lumenis Pulse 30H, with cart Japan	System
RG -2006098	Lumenis Pulse 30H with cart, refurbished	System
GA-1008943	Lumenis Pulse 50H, INT	System
GA-1008946	Lumenis Pulse 50H, DOM	System
GA-1008943CN	Lumenis Pulse 50H, China	System
GA-2006378	Lumenis Pulse 60H, 50Hz	System
GA-2006379	Lumenis Pulse 60H, 60Hz	System
GA-1008942	Lumenis Pulse 100H INT	System
GA-1008944	Lumenis Pulse 100H DOM	System
RG-1008944	Lumenis Pulse 100H, INT, Refurbished	System
RG-1008942	Lumenis Pulse 100H, DOM, Refurbished	System
GA-1008942CN	Lumenis Pulse 100H, China	System



Uygunluk Beyanı

2014/53/AB Direktifi
DoC-1016493

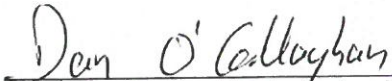
Lumenis Ltd.
Yokneam Industrial Park
Hakidma Street 6,
Yokneam 2069204, Israel

Aşağıdaki telsiz ekipmanı modellerinin 2014/53/AB Direktifindeki ilgili Birlik uyum mevzuatına uygun olduğunu kendi sorumluluğumuz altında beyan ederiz:

AcuPulse DUO (LT-LFS03-SYS-02)
UltraPulse DUO (LT-LFS03-SYS-02)
Lumenis Pulse 100H/50H (LT-LFS03-SYS-06A, LT-LFS03-SYS-06R)
Lumenis Pulse 60H (LT-LFS03-SYS-07)
Lumenis Pulse 30H (LT-LFS03-SYS-09)

Bu uygunluk beyanı ile bağlantılı olarak uygulanan ilgili uyumlaştırılmış standartlar ve/veya teknik özellikler şunlardır:

2014/53/AB Direktifi	Standartlar
Madde 3.1a (Emniyet)	EN 60601-1 EN 50364
Madde 3.1b (Elektromanyetik uyumluluk)	EN 60601-1-2 EN 301 489-1 EN 301 489-3
Madde 3.2 (Spektrum)	EN 300 330


İsim, Vice President - Başkan Yardımcısı,
Ruhsatlandırma ve Kalite

27/July/2022

[Publish Date]

Tarih

Beyanın Geçerlilik Tarihi


İsim, Vice President - Başkan Yardımcısı,
Araştırma ve Geliştirme

28/July/2022

[Publish Date]

Tarih

Beyanın Geçerlilik Tarihi



Katalog Numarası	Ürün Adı	Cihaz Tipi
GA-1000000	AcuPulse DUO	System
GA-1000000CN	AcuPulse DUO CHINA	System
RG-1000000	Refurbish AcuPulse DUO	System
GA-2000000	UltraPulse DUO	System
RG-2000000	Refurbished UltraPulse DUO	System
GA-2006098	Lumenis Pulse 30H with cart	System
GA-2003322	Lumenis Pulse 30H, with cart Japan	System
RG -2006098	Lumenis Pulse 30H with cart, refurbished	System
GA-1008943	Lumenis Pulse 50H, INT	System
GA-1008946	Lumenis Pulse 50H, DOM	System
GA-1008943CN	Lumenis Pulse 50H, China	System
GA-2006378	Lumenis Pulse 60H, 50Hz	System
GA-2006379	Lumenis Pulse 60H, 60Hz	System
GA-1008942	Lumenis Pulse 100H INT	System
GA-1008944	Lumenis Pulse 100H DOM	System
RG-1008944	Lumenis Pulse 100H, INT, Refurbished	System
RG-1008942	Lumenis Pulse 100H, DOM, Refurbished	System
GA-1008942CN	Lumenis Pulse 100H, China	System



Izjava o skladnosti

Direktiva 2014/53/EU

DoC-1016493

Lumenis Ltd.
Yokneam Industrial Park
Hakidma Street 6,
Yokneam 2069204, Israel

Na našo izključno odgovornost izjavljamo, da so naslednji modeli radijske opreme v skladu z ustrezno usklajevalno zakonodajo Unije, kot določa Direktiva 2014/53/EU:

AcuPulse DUO (LT-LFS03-SYS-02)
UltraPulse DUO (LT-LFS03-SYS-02)
Lumenis Pulse 100H/50H (LT-LFS03-SYS-06A, LT-LFS03-SYS-06R)
Lumenis Pulse 60H (LT-LFS03-SYS-07)
Lumenis Pulse 30H (LT-LFS03-SYS-09)

Ustrezni harmonizirani standardi in/ali tehnične specifikacije, ki so uporabljeni v zvezi s to izjavo o skladnosti, so:

Direktiva 2014/53/EU	Standardi
Članek 3.1a (Varnost)	EN 60601-1 EN 50364
Članek 3.1b (Elektromagnetna združljivost)	EN 60601-1-2 EN 301 489-1 EN 301 489-3
Članek 3.2 (Spekter)	EN 300 330

Dan O'Callaghan
Ime, podpredsednik, oddelek za regulativne zadeve in kakovost

27/July/2022
[Publish Date]
Datum

Odi Reznick
Ime, podpredsednik, oddelek za raziskave in razvoj

Datum veljavnosti izjave
28/July/2022
[Publish Date]
Datum

Datum veljavnosti izjave



Kataloška številka	Ime izdelka	Vrsta pripomočka
GA-1000000	AcuPulse DUO	System
GA-1000000CN	AcuPulse DUO CHINA	System
RG-1000000	Refurbish AcuPulse DUO	System
GA-2000000	UltraPulse DUO	System
RG-2000000	Refurbished UltraPulse DUO	System
GA-2006098	Lumenis Pulse 30H with cart	System
GA-2003322	Lumenis Pulse 30H, with cart Japan	System
RG -2006098	Lumenis Pulse 30H with cart, refurbished	System
GA-1008943	Lumenis Pulse 50H, INT	System
GA-1008946	Lumenis Pulse 50H, DOM	System
GA-1008943CN	Lumenis Pulse 50H, China	System
GA-2006378	Lumenis Pulse 60H, 50Hz	System
GA-2006379	Lumenis Pulse 60H, 60Hz	System
GA-1008942	Lumenis Pulse 100H INT	System
GA-1008944	Lumenis Pulse 100H DOM	System
RG-1008944	Lumenis Pulse 100H, INT, Refurbished	System
RG-1008942	Lumenis Pulse 100H, DOM, Refurbished	System
GA-1008942CN	Lumenis Pulse 100H, China	System



Vastavusdeklaratsioon

Direktiiv 2014/53/EL

DoC-1016493

Lumenis Ltd.
Yokneam Industrial Park
Hakidma Street 6,
Yokneam 2069204, Israel

Kinnitame oma ainuvastutusel, et järgmised raadioseadmete mudelid vastavad asjakohastele liidu ühtlustamisõigusaktidele, mis näevad ette direktiivi 2014/53/EL:

AcuPulse DUO (LT-LFS03-SYS-02)
UltraPulse DUO (LT-LFS03-SYS-02)
Lumenis Pulse 100H/50H (LT-LFS03-SYS-06A, LT-LFS03-SYS-06R)
Lumenis Pulse 60H (LT-LFS03-SYS-07)
Lumenis Pulse 30H (LT-LFS03-SYS-09)

Selle vastavusdeklaratsiooniga seoses kohaldatavad asjakohased harmoneeritud standardid ja/või tehnilised kirjeldused on järgmised:

Directive 2014/53/EL	Standardid
Artikkel 3.1a (Ohutus)	EN 60601-1 EN 50364
Artikkel 3.1b (Elektromagnetiline ühilduvus)	EN 60601-1-2 EN 301 489-1 EN 301 489-3
Artikkel 3.2 (Spekter)	EN 300 330

Dan O'Callaghan
Nimi, asepresident regulatiivküsimuste ja
kvaliteedi alal

27/July/2022
[Publish Date]
Kuupäev

Ordi Reznick
Nimi, asepresident teaduse ja arenduse alal

Deklaratsiooni kehtivuskuupäev
28/July/2022
[Publish Date]
Kuupäev

Deklaratsiooni kehtivuskuupäev



Katalooginumber	Toote nimi	Seadme tüüp
GA-1000000	AcuPulse DUO	System
GA-1000000CN	AcuPulse DUO CHINA	System
RG-1000000	Refurbish AcuPulse DUO	System
GA-2000000	UltraPulse DUO	System
RG-2000000	Refurbished UltraPulse DUO	System
GA-2006098	Lumenis Pulse 30H with cart	System
GA-2003322	Lumenis Pulse 30H, with cart Japan	System
RG -2006098	Lumenis Pulse 30H with cart, refurbished	System
GA-1008943	Lumenis Pulse 50H, INT	System
GA-1008946	Lumenis Pulse 50H, DOM	System
GA-1008943CN	Lumenis Pulse 50H, China	System
GA-2006378	Lumenis Pulse 60H, 50Hz	System
GA-2006379	Lumenis Pulse 60H, 60Hz	System
GA-1008942	Lumenis Pulse 100H INT	System
GA-1008944	Lumenis Pulse 100H DOM	System
RG-1008944	Lumenis Pulse 100H, INT, Refurbished	System
RG-1008942	Lumenis Pulse 100H, DOM, Refurbished	System
GA-1008942CN	Lumenis Pulse 100H, China	System



Atbilstības Deklarācija

Direktīva 2014/53/ES

DoC-1016493

Lumenis Ltd.
Yokneam Industrial Park
Hakidma Street 6,
Yokneam 2069204, Israel

Mēs ar pilnu atbildību paziņojam, ka šādi radioiekārtu modeļi atbilst attiecīgajiem Savienības saskaņošanas tiesību aktiem, kas paredz Direktīvu 2014/53/ES:

AcuPulse DUO (LT-LFS03-SYS-02)
UltraPulse DUO (LT-LFS03-SYS-02)
Lumenis Pulse 100H/50H (LT-LFS03-SYS-06A, LT-LFS03-SYS-06R)
Lumenis Pulse 60H (LT-LFS03-SYS-07)
Lumenis Pulse 30H (LT-LFS03-SYS-09)

Attiecīgie saskaņotie standarti un/vai tehniskās specifikācijas, ko piemēro saistībā ar šo atbilstības deklarāciju, ir:

Direktīva 2014/53/ES	Standarti
3.1.a punkts (Drošība)	EN 60601-1 EN 50364
3.1.b punkts (Elektromagnētiskā saderība)	EN 60601-1-2 EN 301 489-1 EN 301 489-3
3.2. punkts (Spektrs)	EN 300 330

Day O'Callaghan
Vārds, viceprezidents, regulatīvie jautājumi
un kvalitāte

27/July/2022
[Publish Date]
Datums

Avdi Reznick
Vārds, viceprezidents, izpēte un attīstība

Deklarācijas spēkā stāšanās
datums
28/July/2022
[Publish Date]
Datums

Deklarācijas spēkā stāšanās
datums



Izstrādājuma nosaukums	Kataloga numurs	Ierīces veids
GA-1000000	AcuPulse DUO	System
GA-1000000CN	AcuPulse DUO CHINA	System
RG-1000000	Refurbish AcuPulse DUO	System
GA-2000000	UltraPulse DUO	System
RG-2000000	Refurbished UltraPulse DUO	System
GA-2006098	Lumenis Pulse 30H with cart	System
GA-2003322	Lumenis Pulse 30H, with cart Japan	System
RG -2006098	Lumenis Pulse 30H with cart, refurbished	System
GA-1008943	Lumenis Pulse 50H, INT	System
GA-1008946	Lumenis Pulse 50H, DOM	System
GA-1008943CN	Lumenis Pulse 50H, China	System
GA-2006378	Lumenis Pulse 60H, 50Hz	System
GA-2006379	Lumenis Pulse 60H, 60Hz	System
GA-1008942	Lumenis Pulse 100H INT	System
GA-1008944	Lumenis Pulse 100H DOM	System
RG-1008944	Lumenis Pulse 100H, INT, Refurbished	System
RG-1008942	Lumenis Pulse 100H, DOM, Refurbished	System
GA-1008942CN	Lumenis Pulse 100H, China	System



Atitikties Deklaracija

Direktyva 2014/53/ES
DoC-1016493

Lumenis Ltd.
Yokneam Industrial Park
Hakidma Street 6,
Yokneam 2069204, Israel

Prisiimdami visišką atsakomybę patvirtiname, kad nurodyti radijo ryšio įranginių modelių atitinka atitinkamus Sąjungos derinimo teisės aktus, nurodytus Direktyvoje 2014/53/ES:

AcuPulse DUO (LT-LFS03-SYS-02)
UltraPulse DUO (LT-LFS03-SYS-02)
Lumenis Pulse 100H/50H (LT-LFS03-SYS-06A, LT-LFS03-SYS-06R)
Lumenis Pulse 60H (LT-LFS03-SYS-07)
Lumenis Pulse 30H (LT-LFS03-SYS-09)

Su šia atitikties deklaracija taikomi atitinkami darnieji standartai ir (arba) techninės specifikacijos:

Direktyva 2014/53/ES	Standartai
Straipsnis 3.1a (Sauga)	EN 60601-1 EN 50364
Straipsnis 3.1b (Elektromagnetinis suderinamumas)	EN 60601-1-2 EN 301 489-1 EN 301 489-3
Straipsnis 3.2 (Spektras)	EN 300 330

Dan O'Callaghan
Vardas ir pavardė, viceprezidentas (-ė),
Reglamentavimo reikalai ir kokybė

27/July/2022
[Publish Date]

Data

Deklaracijos galiojimo data

Odi Reznick
Vardas ir pavardė, viceprezidentas (-ė),
moksliniai tyrimai ir plėtra

28/July/2022
[Publish Date]

Data

Deklaracijos galiojimo data



Katalogo numeris	Gaminio pavadinimas	Prietaiso tipas
GA-1000000	AcuPulse DUO	System
GA-1000000CN	AcuPulse DUO CHINA	System
RG-1000000	Refurbish AcuPulse DUO	System
GA-2000000	UltraPulse DUO	System
RG-2000000	Refurbished UltraPulse DUO	System
GA-2006098	Lumenis Pulse 30H with cart	System
GA-2003322	Lumenis Pulse 30H, with cart Japan	System
RG -2006098	Lumenis Pulse 30H with cart, refurbished	System
GA-1008943	Lumenis Pulse 50H, INT	System
GA-1008946	Lumenis Pulse 50H, DOM	System
GA-1008943CN	Lumenis Pulse 50H, China	System
GA-2006378	Lumenis Pulse 60H, 50Hz	System
GA-2006379	Lumenis Pulse 60H, 60Hz	System
GA-1008942	Lumenis Pulse 100H INT	System
GA-1008944	Lumenis Pulse 100H DOM	System
RG-1008944	Lumenis Pulse 100H, INT, Refurbished	System
RG-1008942	Lumenis Pulse 100H, DOM, Refurbished	System
GA-1008942CN	Lumenis Pulse 100H, China	System



Samræmisýfirlýsing

Tilskipun 2014/53/ESB
DoC-1016493

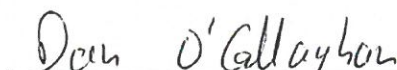
Lumenis Ltd.
Yokneam Industrial Park
Hakidma Street 6,
Yokneam 2069204, Israel

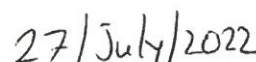
Við lýsum því yfir á okkar eigin ábyrgð að eftirfarandi gerðir af fjarskiptabúnaði eru í samræmi við viðeigandi samþæfingarlöggjöf Sambandsins sem kveður á um tilskipun 2014/53/ESB:

AcuPulse DUO (LT-LFS03-SYS-02)
UltraPulse DUO (LT-LFS03-SYS-02)
Lumenis Pulse 100H/50H (LT-LFS03-SYS-06A, LT-LFS03-SYS-06R)
Lumenis Pulse 60H (LT-LFS03-SYS-07)
Lumenis Pulse 30H (LT-LFS03-SYS-09)

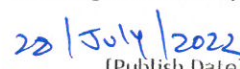
Viðeigandi samþæfðir staðlar og/eða tækniforskriftir sem notaðar eru í tengslum við þessa samræmisýfirlýsingu eru:

Tilskipun 2014/53/ESB	Staðlar
Gr 3.1a (Öryggi)	EN 60601-1 EN 50364
Gr 3.1b (Rafsegulsamþæfni)	EN 60601-1-2 EN 301 489-1 EN 301 489-3
Gr 3.2 (Litróf)	EN 300 330


Nafn, varaforseti, reglu- og gæðamál


[Publish Date]
Dagsetning


Nafn, varaforseti, rannsóknir og þróun

Gildisdagur samræmisýfirlýsingar

[Publish Date]
Dagsetning

Gildisdagur samræmisýfirlýsingar



Vörulista- Númer	Vöruheiti	Tegund búnaðar
GA-1000000	AcuPulse DUO	System
GA-1000000CN	AcuPulse DUO CHINA	System
RG-1000000	Refurbish AcuPulse DUO	System
GA-2000000	UltraPulse DUO	System
RG-2000000	Refurbished UltraPulse DUO	System
GA-2006098	Lumenis Pulse 30H with cart	System
GA-2003322	Lumenis Pulse 30H, with cart Japan	System
RG -2006098	Lumenis Pulse 30H with cart, refurbished	System
GA-1008943	Lumenis Pulse 50H, INT	System
GA-1008946	Lumenis Pulse 50H, DOM	System
GA-1008943CN	Lumenis Pulse 50H, China	System
GA-2006378	Lumenis Pulse 60H, 50Hz	System
GA-2006379	Lumenis Pulse 60H, 60Hz	System
GA-1008942	Lumenis Pulse 100H INT	System
GA-1008944	Lumenis Pulse 100H DOM	System
RG-1008944	Lumenis Pulse 100H, INT, Refurbished	System
RG-1008942	Lumenis Pulse 100H, DOM, Refurbished	System
GA-1008942CN	Lumenis Pulse 100H, China	System