



Description: Lumenis Pulse 120H RED DoC cover page

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Lumenis Pulse 120H

Radio Equipment Directive 2014/53/EU Declaration - Ltd

1. Certificate Details

Test Article(s)	<i>Lumenis Pulse 120H</i>
Applicable Standard(s)	<i>Radio Equipment Directive 2014/53/EU</i>
Certificate Issue Date	<i>30 May 2022</i>
Certificate Number	<i>1015589</i>

2. Reference Documents

Enovia Document Number	Document Description
<i>NA</i>	<i>NA</i>

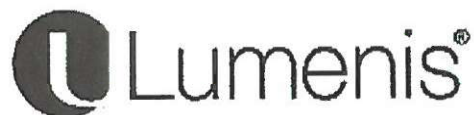
3. Revision History

Revision	Reason of Change
A	Initiation Release.
B	- Updated RED DoC for RFID and cellular modem, as per the RED file - Added EU member state translations to the DoC



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Declaration of Conformity

Directive 2014/53/EU
DoC-1015589

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:

Lumenis Pulse 120H (LT-LFS03-SYS-05, LM940)

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 EN 62311
Article 3.1b (EMC)	EN 60601-1-2 EN 301 489-1 EN 301 489-3 EN 301 489-52
Article 3.2 (Spectrum)	EN 300 330

Dan O'Callaghan (Director, QA/RA)
Name, VP, Regulatory Affairs and Quality
Signing for V.P.

23 May 2022
Date

Declaration Validity Date

Dudi Rernick (Director R.D.)
Name, VP, Research & Development
Signing for VP

30 May 2022
Date

Declaration Validity Date



Catalog Number	Product Name	Device Type
GA-0006900	Lumenis Pulse 120H, INT 1PH	System
GA-0006800	Lumenis Pulse 120H, DOM 1PH	System
GA-0008800	Lumenis Pulse 120H, INT 3PH	System
GA-0006801	Lumenis Pulse 120H, DOM 1PH with Moses	System
RG-0006801	Lumenis Pulse 120H, DOM 1PH with Moses, Refurbished	System
GA-2003477	Lumenis Pulse 120H, INT 1PH No Suction	System
GA-2003476	Lumenis Pulse 120H, DOM 1PH No suction	System
GA-0008700	Lumenis Pulse 120H, INT 1PH 32A	System
GA-0006900CN	Lumenis Pulse 120H, 1PH, China	System
RG-0006900	Lumenis Pulse 120H, INT, 1PH, Refurbished	System
RG-0008800	Lumenis Pulse 120H, INT, 3PH, Refurbished	System
RG-0006800	Lumenis Pulse 120H, DOM 1PH, Refurbished	System
GA-2009996	Lumenis Pulse 120H, DOM 1 PH 30A	System
GA-0006902	Lumenis Pulse 120H, MOSES 2.0 (INT)	System
GA-0006802	Lumenis Pulse 120H, MOSES 2.0 (DOM)	System



Konformitätserklärung

Richtlinie 2014/53/EU
DoC-1015589

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:

Lumenis Pulse 120H (LT-LFS03-SYS-05, LM940)

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 EN 62311
Artikel 3.1b (Elektromagnetische Verträglichkeit)	EN 60601-1-2 EN 301 489-1 EN 301 489-3 EN 301 489-52
Artikel 3.2 (Spektrum)	EN 300 330

Don O'Callaghan (Director QA/RA)

Name, VP, Regulatorische Angelegenheiten
und Qualität

Signing for VP

23 May 2022

Datum

Gültigkeitsdatum der Erklärung

Dudi Reznick (Director R&D)

Name, VP, Forschung & Entwicklung

Signing for VP

30 May 2022

Datum

Gültigkeitsdatum der Erklärung



Bestell-Nr.	Produktname	Gerätetyp
GA-0006900	Lumenis Pulse 120H, INT 1PH	System
GA-0006800	Lumenis Pulse 120H, DOM 1PH	System
GA-0008800	Lumenis Pulse 120H, INT 3PH	System
GA-0006801	Lumenis Pulse 120H, DOM 1PH with Moses	System
RG-0006801	Lumenis Pulse 120H, DOM 1PH with Moses, Refurbished	System
GA-2003477	Lumenis Pulse 120H, INT 1PH No Suction	System
GA-2003476	Lumenis Pulse 120H, DOM 1PH No suction	System
GA-0008700	Lumenis Pulse 120H, INT 1PH 32A	System
GA-0006900CN	Lumenis Pulse 120H, 1PH, China	System
RG-0006900	Lumenis Pulse 120H, INT, 1PH, Refurbished	System
RG-0008800	Lumenis Pulse 120H, INT, 3PH, Refurbished	System
RG-0006800	Lumenis Pulse 120H, DOM 1PH, Refurbished	System
GA-2009996	Lumenis Pulse 120H, DOM 1 PH 30A	System
GA-0006902	Lumenis Pulse 120H, MOSES 2.0 (INT)	System
GA-0006802	Lumenis Pulse 120H, MOSES 2.0 (DOM)	System



Déclaration de Conformité

Directive 2014/53/UE

DoC-1015589

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:

Lumenis Pulse 120H (LT-LFS03-SYS-05, LM940)

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 EN 62311
Article 3.1b (Compatibilité électromagnétique)	EN 60601-1-2 EN 301 489-1 EN 301 489-3 EN 301 489-52
Article 3.2 (Spectre)	EN 300 330

Dan O'Callaghan (Director QA/RA)
Nom, VP, Affaires réglementaires et Qualité
Signing for VP

23/May/2022
Date

Date de validité de la
déclaration

Dudi Reznick (Director R&D)
Nom, VP, Recherche et Développement
Signing for VP

30/May/2022
Date

Date de validité de la
déclaration



Référence catalogue	Nom du produit	Type de dispositif
GA-0006900	Lumenis Pulse 120H, INT 1PH	System
GA-0006800	Lumenis Pulse 120H, DOM 1PH	System
GA-0008800	Lumenis Pulse 120H, INT 3PH	System
GA-0006801	Lumenis Pulse 120H, DOM 1PH with Moses	System
RG-0006801	Lumenis Pulse 120H, DOM 1PH with Moses, Refurbished	System
GA-2003477	Lumenis Pulse 120H, INT 1PH No Suction	System
GA-2003476	Lumenis Pulse 120H, DOM 1PH No suction	System
GA-0008700	Lumenis Pulse 120H, INT 1PH 32A	System
GA-0006900CN	Lumenis Pulse 120H, 1PH, China	System
RG-0006900	Lumenis Pulse 120H, INT, 1PH, Refurbished	System
RG-0008800	Lumenis Pulse 120H, INT, 3PH, Refurbished	System
RG-0006800	Lumenis Pulse 120H, DOM 1PH, Refurbished	System
GA-2009996	Lumenis Pulse 120H, DOM 1 PH 30A	System
GA-0006902	Lumenis Pulse 120H, MOSES 2.0 (INT)	System
GA-0006802	Lumenis Pulse 120H, MOSES 2.0 (DOM)	System



Declaración De Conformidad

Directiva 2014/53/UE

DoC-1015589

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:

Lumenis Pulse 120H (LT-LFS03-SYS-05, LM940)

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 EN 62311
Artículo 3.1b (Compatibilidad electromagnética)	EN 60601-1-2 EN 301 489-1 EN 301 489-3 EN 301 489-52
Artículo 3.2 (Espectro)	EN 300 330

Dean O'Callaghan (Director QA/QA)
Nombre, VP, Asuntos Regulatorios y de Calidad
Signing for VP

23/May/2022

Fecha

Fecha de validez de la
declaración

Ovidi Reznick (Director R&D)
Nombre, VP, Investigación y Desarrollo
Signing for VP

30/May/2022
Fecha

Fecha de validez de la
declaración



Número de catálogo	Nombre del producto	Tipo de dispositivo
GA-0006900	Lumenis Pulse 120H, INT 1PH	System
GA-0006800	Lumenis Pulse 120H, DOM 1PH	System
GA-0008800	Lumenis Pulse 120H, INT 3PH	System
GA-0006801	Lumenis Pulse 120H, DOM 1PH with Moses	System
RG-0006801	Lumenis Pulse 120H, DOM 1PH with Moses, Refurbished	System
GA-2003477	Lumenis Pulse 120H, INT 1PH No Suction	System
GA-2003476	Lumenis Pulse 120H, DOM 1PH No suction	System
GA-0008700	Lumenis Pulse 120H, INT 1PH 32A	System
GA-0006900CN	Lumenis Pulse 120H, 1PH, China	System
RG-0006900	Lumenis Pulse 120H, INT, 1PH, Refurbished	System
RG-0008800	Lumenis Pulse 120H, INT, 3PH, Refurbished	System
RG-0006800	Lumenis Pulse 120H, DOM 1PH, Refurbished	System
GA-2009996	Lumenis Pulse 120H, DOM 1 PH 30A	System
GA-0006902	Lumenis Pulse 120H, MOSES 2.0 (INT)	System
GA-0006802	Lumenis Pulse 120H, MOSES 2.0 (DOM)	System



Dichiarazione di Conformità

Direttiva 2014/53/UE

DoC-1015589

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:

Lumenis Pulse 120H (LT-LFS03-SYS-05, LM940)

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 EN 62311
Articolo 3.1b (Compatibilità elettromagnetica)	EN 60601-1-2 EN 301 489-1 EN 301 489-3 EN 301 489-52
Articolo 3.2 (Spettro)	EN 300 330

Dan O'Callaghan (Director QA/RA)
Nome, VP, Affari regolatori e Qualità
Signing for VP

23/May/2022

Data

Data di entrata in vigore della
dichiarazione

Dudi Reznick (Director R&D)
Nome, VP, Ricerca e Sviluppo
Signing for VP

30/May/2022

Data

Data di entrata in vigore della
dichiarazione



Numero di catalogo	Nome del prodotto	Tipo di dispositivo
GA-0006900	Lumenis Pulse 120H, INT 1PH	System
GA-0006800	Lumenis Pulse 120H, DOM 1PH	System
GA-0008800	Lumenis Pulse 120H, INT 3PH	System
GA-0006801	Lumenis Pulse 120H, DOM 1PH with Moses	System
RG-0006801	Lumenis Pulse 120H, DOM 1PH with Moses, Refurbished	System
GA-2003477	Lumenis Pulse 120H, INT 1PH No Suction	System
GA-2003476	Lumenis Pulse 120H, DOM 1PH No suction	System
GA-0008700	Lumenis Pulse 120H, INT 1PH 32A	System
GA-0006900CN	Lumenis Pulse 120H, 1PH, China	System
RG-0006900	Lumenis Pulse 120H, INT, 1PH, Refurbished	System
RG-0008800	Lumenis Pulse 120H, INT, 3PH, Refurbished	System
RG-0006800	Lumenis Pulse 120H, DOM 1PH, Refurbished	System
GA-2009996	Lumenis Pulse 120H, DOM 1 PH 30A	System
GA-0006902	Lumenis Pulse 120H, MOSES 2.0 (INT)	System
GA-0006802	Lumenis Pulse 120H, MOSES 2.0 (DOM)	System



CE-Conformiteitsverklaring

Richtlijn 2014/53/EU

DoC-1015589

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:

Lumenis Pulse 120H (LT-LFS03-SYS-05, LM940)

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 EN 62311
Artikel 3.1b (Elektromagnetische compatibiliteit)	EN 60601-1-2 EN 301 489-1 EN 301 489-3 EN 301 489-52
Artikel 3.2 (Spectrum)	EN 300 330

Dan O'Callaghan (Director QA/QA)
Naam, VP, Regelgevende Zaken en Kwaliteit
Signing for VP

23/ May/2022
Datum

Geldigheidsdatum verklaring

Dvdi Reznick (Director R.D)
Naam, VP, Onderzoek & Ontwikkeling
Signing for VP

30/ May/2022
Datum

Geldigheidsdatum verklaring



Catalogus-nummer	Productnaam	Type Hulpmiddel
GA-0006900	Lumenis Pulse 120H, INT 1PH	System
GA-0006800	Lumenis Pulse 120H, DOM 1PH	System
GA-0008800	Lumenis Pulse 120H, INT 3PH	System
GA-0006801	Lumenis Pulse 120H, DOM 1PH with Moses	System
RG-0006801	Lumenis Pulse 120H, DOM 1PH with Moses, Refurbished	System
GA-2003477	Lumenis Pulse 120H, INT 1PH No Suction	System
GA-2003476	Lumenis Pulse 120H, DOM 1PH No suction	System
GA-0008700	Lumenis Pulse 120H, INT 1PH 32A	System
GA-0006900CN	Lumenis Pulse 120H, 1PH, China	System
RG-0006900	Lumenis Pulse 120H, INT, 1PH, Refurbished	System
RG-0008800	Lumenis Pulse 120H, INT, 3PH, Refurbished	System
RG-0006800	Lumenis Pulse 120H, DOM 1PH, Refurbished	System
GA-2009996	Lumenis Pulse 120H, DOM 1 PH 30A	System
GA-0006902	Lumenis Pulse 120H, MOSES 2.0 (INT)	System
GA-0006802	Lumenis Pulse 120H, MOSES 2.0 (DOM)	System



Declaração de Conformidade

Diretiva 2014/53/UE

DoC-1015589

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:

Lumenis Pulse 120H (LT-LFS03-SYS-05, LM940)

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 EN 62311
Artigo n.º 3.1b (Compatibilidade eletromagnética)	EN 60601-1-2 EN 301 489-1 EN 301 489-3 EN 301 489-52
Artigo n.º 3.2 (Espectro)	EN 300 330

Dan O'Callaghan (Director QA/QA)
Nome, VP, Assuntos Regulamentares e
Qualidade

Signing for VP

23 May 2022
Data

Data de validade da declaração

Oudi Reznick (Director R&D)
Nome, VP, Investigação e Desenvolvimento
Signing for VP

30 May 2022
Data

Data de validade da declaração



Referência	Nome do produto	Tipo de dispositivo
GA-0006900	Lumenis Pulse 120H, INT 1PH	System
GA-0006800	Lumenis Pulse 120H, DOM 1PH	System
GA-0008800	Lumenis Pulse 120H, INT 3PH	System
GA-0006801	Lumenis Pulse 120H, DOM 1PH with Moses	System
RG-0006801	Lumenis Pulse 120H, DOM 1PH with Moses, Refurbished	System
GA-2003477	Lumenis Pulse 120H, INT 1PH No Suction	System
GA-2003476	Lumenis Pulse 120H, DOM 1PH No suction	System
GA-0008700	Lumenis Pulse 120H, INT 1PH 32A	System
GA-0006900CN	Lumenis Pulse 120H, 1PH, China	System
RG-0006900	Lumenis Pulse 120H, INT, 1PH, Refurbished	System
RG-0008800	Lumenis Pulse 120H, INT, 3PH, Refurbished	System
RG-0006800	Lumenis Pulse 120H, DOM 1PH, Refurbished	System
GA-2009996	Lumenis Pulse 120H, DOM 1 PH 30A	System
GA-0006902	Lumenis Pulse 120H, MOSES 2.0 (INT)	System
GA-0006802	Lumenis Pulse 120H, MOSES 2.0 (DOM)	System



ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ

Οδηγία 2014/53/ΕΕ
DoC-1015589

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/ΕΕ:

Lumenis Pulse 120H (LT-LFS03-SYS-05, LM940)

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

Οδηγία 2014/53/ΕΕ	Πρότυπα
Άρθρο 3.1a (Ασφάλεια)	EN 60601-1 EN 50364 EN 62311
Άρθρο 3.1b (Ηλεκτρομαγνητική συμβατότητα)	EN 60601-1-2 EN 301 489-1 EN 301 489-3 EN 301 489-52
Άρθρο 3.2 (Φάσμα)	EN 300 330

Dan O'Callaghan (Director QA/QA)
Όνομα, Αντιπρόεδρος, Κανονιστικές Υποθέσεις
και Ποιότητα
Signing for VP

23 May 2022
Ημερομηνία

Ημερομηνία ισχύος δήλωσης

Dudi Reznick (Director R&D)
Όνομα, Αντιπρόεδρος, Έρευνα και Ανάπτυξη
Signing for VP

30 May 2022
Ημερομηνία

Ημερομηνία ισχύος δήλωσης



Αριθμός καταλόγου	Όνομα προϊόντος	Τύπος συσκευής
GA-0006900	Lumenis Pulse 120H, INT 1PH	System
GA-0006800	Lumenis Pulse 120H, DOM 1PH	System
GA-0008800	Lumenis Pulse 120H, INT 3PH	System
GA-0006801	Lumenis Pulse 120H, DOM 1PH with Moses	System
RG-0006801	Lumenis Pulse 120H, DOM 1PH with Moses, Refurbished	System
GA-2003477	Lumenis Pulse 120H, INT 1PH No Suction	System
GA-2003476	Lumenis Pulse 120H, DOM 1PH No suction	System
GA-0008700	Lumenis Pulse 120H, INT 1PH 32A	System
GA-0006900CN	Lumenis Pulse 120H, 1PH, China	System
RG-0006900	Lumenis Pulse 120H, INT, 1PH, Refurbished	System
RG-0008800	Lumenis Pulse 120H, INT, 3PH, Refurbished	System
RG-0006800	Lumenis Pulse 120H, DOM 1PH, Refurbished	System
GA-2009996	Lumenis Pulse 120H, DOM 1 PH 30A	System
GA-0006902	Lumenis Pulse 120H, MOSES 2.0 (INT)	System
GA-0006802	Lumenis Pulse 120H, MOSES 2.0 (DOM)	System



Samsvarserklæring

Direktiv 2014/53/EU
DoC-1015589

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:

Lumenis Pulse 120H (LT-LFS03-SYS-05, LM940)

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 EN 62311
Artikkel 3.1b (Elektromagnetisk kompatibilitet)	EN 60601-1-2 EN 301 489-1 EN 301 489-3 EN 301 489-52
Artikkel 3.2 (Spektrum)	EN 300 330

Day O'Callaghan (Director QA/RA)

Navn, VP, regulatoriske forhold og kvalitet

Signering for VP

23/May/2022

Dato

Gyldighetsdato for erklæring

Dudi Rendaick (Director R&D)

Navn, VP, forskning og utvikling

Signering for VP

30/May/2022

Dato

Gyldighetsdato for erklæring



Katalognummer	Produktnavn	Enhetstype
GA-0006900	Lumenis Pulse 120H, INT 1PH	System
GA-0006800	Lumenis Pulse 120H, DOM 1PH	System
GA-0008800	Lumenis Pulse 120H, INT 3PH	System
GA-0006801	Lumenis Pulse 120H, DOM 1PH with Moses	System
RG-0006801	Lumenis Pulse 120H, DOM 1PH with Moses, Refurbished	System
GA-2003477	Lumenis Pulse 120H, INT 1PH No Suction	System
GA-2003476	Lumenis Pulse 120H, DOM 1PH No suction	System
GA-0008700	Lumenis Pulse 120H, INT 1PH 32A	System
GA-0006900CN	Lumenis Pulse 120H, 1PH, China	System
RG-0006900	Lumenis Pulse 120H, INT, 1PH, Refurbished	System
RG-0008800	Lumenis Pulse 120H, INT, 3PH, Refurbished	System
RG-0006800	Lumenis Pulse 120H, DOM 1PH, Refurbished	System
GA-2009996	Lumenis Pulse 120H, DOM 1 PH 30A	System
GA-0006902	Lumenis Pulse 120H, MOSES 2.0 (INT)	System
GA-0006802	Lumenis Pulse 120H, MOSES 2.0 (DOM)	System



Overensstemmelseserklæring

Direktiv 2014/53/EU

DoC-1015589

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

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

Lumenis Pulse 120H (LT-LFS03-SYS-05, LM940)

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 EN 62311
Artikel 3.1b (Elektromagnetisk kompatibilitet)	EN 60601-1-2 EN 301 489-1 EN 301 489-3 EN 301 489-52
Artikel 3.2 (Spektrum)	EN 300 330

Don O' Callaghan (Director QA/QA)
Navn, vicedirektør, retsforskrifter og kvalitet
Signering for VP

23/May/2022
Dato

Erklæringens
ikrafttrædelsesdato

Dudi Reznick (Director R&D)
Navn, vicedirektør, forskning og udvikling
Signering for VP

30/May/2022
Dato

Erklæringens
ikrafttrædelsesdato



Katalognummer	Produktnavn	Enhedstype
GA-0006900	Lumenis Pulse 120H, INT 1PH	System
GA-0006800	Lumenis Pulse 120H, DOM 1PH	System
GA-0008800	Lumenis Pulse 120H, INT 3PH	System
GA-0006801	Lumenis Pulse 120H, DOM 1PH with Moses	System
RG-0006801	Lumenis Pulse 120H, DOM 1PH with Moses, Refurbished	System
GA-2003477	Lumenis Pulse 120H, INT 1PH No Suction	System
GA-2003476	Lumenis Pulse 120H, DOM 1PH No suction	System
GA-0008700	Lumenis Pulse 120H, INT 1PH 32A	System
GA-0006900CN	Lumenis Pulse 120H, 1PH, China	System
RG-0006900	Lumenis Pulse 120H, INT, 1PH, Refurbished	System
RG-0008800	Lumenis Pulse 120H, INT, 3PH, Refurbished	System
RG-0006800	Lumenis Pulse 120H, DOM 1PH, Refurbished	System
GA-2009996	Lumenis Pulse 120H, DOM 1 PH 30A	System
GA-0006902	Lumenis Pulse 120H, MOSES 2.0 (INT)	System
GA-0006802	Lumenis Pulse 120H, MOSES 2.0 (DOM)	System



Försäkran om överensstämmelse

Direktiv 2014/53/EU

DoC-1015589

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:

Lumenis Pulse 120H (LT-LFS03-SYS-05, LM940)

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 EN 62311
Artikel 3.1b (Elektromagnetisk kompatibilitet)	EN 60601-1-2 EN 301 489-1 EN 301 489-3 EN 301 489-52
Artikel 3.2 (Spektrum)	EN 300 330

Don O'Callaghan (Director QA/RA)
Namn, VP för regleringsfrågor och kvalitet
Signering för VP

23/May/2022
Datum

Giltighetsdatum för försäkran

Dudi Reznick (Director R&D)
Namn, VP för forskning och utveckling
Signering för VP

30/May/2022
Datum

Giltighetsdatum för försäkran



Katalognummer	Produktnamn	Enhetstyp
GA-0006900	Lumenis Pulse 120H, INT 1PH	System
GA-0006800	Lumenis Pulse 120H, DOM 1PH	System
GA-0008800	Lumenis Pulse 120H, INT 3PH	System
GA-0006801	Lumenis Pulse 120H, DOM 1PH with Moses	System
RG-0006801	Lumenis Pulse 120H, DOM 1PH with Moses, Refurbished	System
GA-2003477	Lumenis Pulse 120H, INT 1PH No Suction	System
GA-2003476	Lumenis Pulse 120H, DOM 1PH No suction	System
GA-0008700	Lumenis Pulse 120H, INT 1PH 32A	System
GA-0006900CN	Lumenis Pulse 120H, 1PH, China	System
RG-0006900	Lumenis Pulse 120H, INT, 1PH, Refurbished	System
RG-0008800	Lumenis Pulse 120H, INT, 3PH, Refurbished	System
RG-0006800	Lumenis Pulse 120H, DOM 1PH, Refurbished	System
GA-2009996	Lumenis Pulse 120H, DOM 1 PH 30A	System
GA-0006902	Lumenis Pulse 120H, MOSES 2.0 (INT)	System
GA-0006802	Lumenis Pulse 120H, MOSES 2.0 (DOM)	System



Vyhlásenie o Zhode

Smernica 2014/53/EÚ
DoC-1015589

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:

Lumenis Pulse 120H (LT-LFS03-SYS-05, LM940)

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 EN 62311
Článku 3.1b (Elektromagnetická kompatibilita)	EN 60601-1-2 EN 301 489-1 EN 301 489-3 EN 301 489-52
Článku 3.2 (Spektrum)	EN 300 330

Devin O'Callaghan (Director QA/QA)
Meno, VP, regulačné záležitosti a kvalita
Signing for VP

23/May/2022
Dátum

Dátum platnosti vyhlásenia

Dudi Reznick (Director R&D)
Meno, VP, výskum a vývoj
Signing for VP

30/May/2022
Dátum

Dátum platnosti vyhlásenia



Katalógové číslo	Názov produktu	Typ pomôcky
GA-0006900	Lumenis Pulse 120H, INT 1PH	System
GA-0006800	Lumenis Pulse 120H, DOM 1PH	System
GA-0008800	Lumenis Pulse 120H, INT 3PH	System
GA-0006801	Lumenis Pulse 120H, DOM 1PH with Moses	System
RG-0006801	Lumenis Pulse 120H, DOM 1PH with Moses, Refurbished	System
GA-2003477	Lumenis Pulse 120H, INT 1PH No Suction	System
GA-2003476	Lumenis Pulse 120H, DOM 1PH No suction	System
GA-0008700	Lumenis Pulse 120H, INT 1PH 32A	System
GA-0006900CN	Lumenis Pulse 120H, 1PH, China	System
RG-0006900	Lumenis Pulse 120H, INT, 1PH, Refurbished	System
RG-0008800	Lumenis Pulse 120H, INT, 3PH, Refurbished	System
RG-0006800	Lumenis Pulse 120H, DOM 1PH, Refurbished	System
GA-2009996	Lumenis Pulse 120H, DOM 1 PH 30A	System
GA-0006902	Lumenis Pulse 120H, MOSES 2.0 (INT)	System
GA-0006802	Lumenis Pulse 120H, MOSES 2.0 (DOM)	System



Prohlášení o Shodě

Směrnice 2014/53/EU
DoC-1015589

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:

Lumenis Pulse 120H (LT-LFS03-SYS-05, LM940)

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

Směrnice 2014/53/EU	Normy
Článek 3.1a (Bezpečnost)	EN 60601-1 EN 50364 EN 62311
Článek 3.1b (Elektromagnetická kompatibilita)	EN 60601-1-2 EN 301 489-1 EN 301 489-3 EN 301 489-52
Článek 3.2 (Spektrum)	EN 300 330

Dan O'Callaghan (Director QA/RA)
Jméno, VP, Regulační záležitosti a kvalita
Signing for VP

23 May 2022
Datum

Datum platnosti prohlášení

Dvdi Reznick (Director RnD)
Jméno, VP, Výzkum a vývoj
Signing for VP

30 May 2022
Datum

Datum platnosti prohlášení



Katalogové číslo	Název produktu	Typ zařízení
GA-0006900	Lumenis Pulse 120H, INT 1PH	System
GA-0006800	Lumenis Pulse 120H, DOM 1PH	System
GA-0008800	Lumenis Pulse 120H, INT 3PH	System
GA-0006801	Lumenis Pulse 120H, DOM 1PH with Moses	System
RG-0006801	Lumenis Pulse 120H, DOM 1PH with Moses, Refurbished	System
GA-2003477	Lumenis Pulse 120H, INT 1PH No Suction	System
GA-2003476	Lumenis Pulse 120H, DOM 1PH No suction	System
GA-0008700	Lumenis Pulse 120H, INT 1PH 32A	System
GA-0006900CN	Lumenis Pulse 120H, 1PH, China	System
RG-0006900	Lumenis Pulse 120H, INT, 1PH, Refurbished	System
RG-0008800	Lumenis Pulse 120H, INT, 3PH, Refurbished	System
RG-0006800	Lumenis Pulse 120H, DOM 1PH, Refurbished	System
GA-2009996	Lumenis Pulse 120H, DOM 1 PH 30A	System
GA-0006902	Lumenis Pulse 120H, MOSES 2.0 (INT)	System
GA-0006802	Lumenis Pulse 120H, MOSES 2.0 (DOM)	System



Megfelelőségi nyilatkozat

2014/53/EU irányelv
DoC-1015589

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 Unió harmonizációs jogszabályoknak:

Lumenis Pulse 120H (LT-LFS03-SYS-05, LM940)

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 EN 62311
3.(1) b cikk (Elektromágneses kompatibilitás)	EN 60601-1-2 EN 301 489-1 EN 301 489-3 EN 301 489-52
3.(2) cikk (Spektrum)	EN 300 330

Dan O'Callaghan (Director QA/RA)
Név, ügyv. ig., Szabályozói ügyek és
Minőségellenőrzés

Signing for VP

23 / May / 2022
Dátum

Nyilatkozat érvényességi
dátuma

Dudi Reznick (Director R.D.)
Név, ügyv. ig., Kutatás, fejlesztés
Signing for VP

30 / May / 2022
Dátum

Nyilatkozat érvényességi
dátuma



Katalógusszám	Terméknév	Eszköztípus
GA-0006900	Lumenis Pulse 120H, INT 1PH	System
GA-0006800	Lumenis Pulse 120H, DOM 1PH	System
GA-0008800	Lumenis Pulse 120H, INT 3PH	System
GA-0006801	Lumenis Pulse 120H, DOM 1PH with Moses	System
RG-0006801	Lumenis Pulse 120H, DOM 1PH with Moses, Refurbished	System
GA-2003477	Lumenis Pulse 120H, INT 1PH No Suction	System
GA-2003476	Lumenis Pulse 120H, DOM 1PH No suction	System
GA-0008700	Lumenis Pulse 120H, INT 1PH 32A	System
GA-0006900CN	Lumenis Pulse 120H, 1PH, China	System
RG-0006900	Lumenis Pulse 120H, INT, 1PH, Refurbished	System
RG-0008800	Lumenis Pulse 120H, INT, 3PH, Refurbished	System
RG-0006800	Lumenis Pulse 120H, DOM 1PH, Refurbished	System
GA-2009996	Lumenis Pulse 120H, DOM 1 PH 30A	System
GA-0006902	Lumenis Pulse 120H, MOSES 2.0 (INT)	System
GA-0006802	Lumenis Pulse 120H, MOSES 2.0 (DOM)	System



Vaatimustenmukaisuusvakuutus

Direktiivi 2014/53/EU

DoC-1015589

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:

Lumenis Pulse 120H (LT-LFS03-SYS-05, LM940)

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

Direktiivi 2014/53/EU	Standardit
Artikla 3.1a (Turvallisuus)	EN 60601-1 EN 50364 EN 62311
Artikla 3.1b (Elektromagneettinen yhteensopivuus)	EN 60601-1-2 EN 301 489-1 EN 301 489-3 EN 301 489-52
Artikla 3.2 (Spektri)	EN 300 330

Dan O'Callaghan (Director QA/RA)
Nimi, VP, sääntelyasiat ja laatu

Signing for VP

23 May 2022

Päivämäärä

Vakuutuksen voimaantulopäivä

Rudi Reznick (Director R&D)
Nimi, VP, tutkimus ja kehitys

signing for VP

30 May 2022

Päivämäärä

Vakuutuksen voimaantulopäivä



Luettelonumero	Tuotteen nimi	Laitteen tyyppi
GA-0006900	Lumenis Pulse 120H, INT 1PH	System
GA-0006800	Lumenis Pulse 120H, DOM 1PH	System
GA-0008800	Lumenis Pulse 120H, INT 3PH	System
GA-0006801	Lumenis Pulse 120H, DOM 1PH with Moses	System
RG-0006801	Lumenis Pulse 120H, DOM 1PH with Moses, Refurbished	System
GA-2003477	Lumenis Pulse 120H, INT 1PH No Suction	System
GA-2003476	Lumenis Pulse 120H, DOM 1PH No suction	System
GA-0008700	Lumenis Pulse 120H, INT 1PH 32A	System
GA-0006900CN	Lumenis Pulse 120H, 1PH, China	System
RG-0006900	Lumenis Pulse 120H, INT, 1PH, Refurbished	System
RG-0008800	Lumenis Pulse 120H, INT, 3PH, Refurbished	System
RG-0006800	Lumenis Pulse 120H, DOM 1PH, Refurbished	System
GA-2009996	Lumenis Pulse 120H, DOM 1 PH 30A	System
GA-0006902	Lumenis Pulse 120H, MOSES 2.0 (INT)	System
GA-0006802	Lumenis Pulse 120H, MOSES 2.0 (DOM)	System



Deklaracja zgodności

Dyrektywa 2014/53/UE

DoC-1015589

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:

Lumenis Pulse 120H (LT-LF503-SYS-05, LM940)

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 EN 62311
Artykuł 3.1b (Kompatybilność elektromagnetyczna)	EN 60601-1-2 EN 301 489-1 EN 301 489-3 EN 301 489-52
Artykuł 3.2 (Widmo)	EN 300 330

Dan O'Callaghan (Director QA/RA) 23/May/2022
Imię i nazwisko wiceprezesa ds. regulacyjnych i kontroli jakości Data

Signing for VP

Data ważności deklaracji

Pati Reznick (Director R.D.) 30/May/2022
Imię i nazwisko wiceprezesa ds. badań i rozwoju Data

Signing for VP

Data ważności deklaracji



Numer katalogowy	Nazwa produktu	Rodzaj urządzenia
GA-0006900	Lumenis Pulse 120H, INT 1PH	System
GA-0006800	Lumenis Pulse 120H, DOM 1PH	System
GA-0008800	Lumenis Pulse 120H, INT 3PH	System
GA-0006801	Lumenis Pulse 120H, DOM 1PH with Moses	System
RG-0006801	Lumenis Pulse 120H, DOM 1PH with Moses, Refurbished	System
GA-2003477	Lumenis Pulse 120H, INT 1PH No Suction	System
GA-2003476	Lumenis Pulse 120H, DOM 1PH No suction	System
GA-0008700	Lumenis Pulse 120H, INT 1PH 32A	System
GA-0006900CN	Lumenis Pulse 120H, 1PH, China	System
RG-0006900	Lumenis Pulse 120H, INT, 1PH, Refurbished	System
RG-0008800	Lumenis Pulse 120H, INT, 3PH, Refurbished	System
RG-0006800	Lumenis Pulse 120H, DOM 1PH, Refurbished	System
GA-2009996	Lumenis Pulse 120H, DOM 1 PH 30A	System
GA-0006902	Lumenis Pulse 120H, MOSES 2.0 (INT)	System
GA-0006802	Lumenis Pulse 120H, MOSES 2.0 (DOM)	System



Декларация за съответствие

Директива 2014/53/ЕС
DoC-1015589

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/ЕС:

Lumenis Pulse 120H (LT-LFS03-SYS-05, LM940)

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

Директива 2014/53/ЕС	Стандарти
Член 3.1а (Безопасност)	EN 60601-1 EN 50364 EN 62311
Член 3.1b (Електромагнитна съвместимост)	EN 60601-1-2 EN 301 489-1 EN 301 489-3 EN 301 489-52
Член 3.2 (Спектър)	EN 300 330

Dan O'Callaghan (Director QA/RA)

Име, Вицепрезидент по регулаторни
дейности и качество

Signing for VP

23/ May /2022

Дата

Дата на валидност на
декларацията

Dudi Reznick (Director R&D)

Име, Вицепрезидент по изследователски
дейности и разработка

Signing for VP

30/ May /2022

Дата

Дата на валидност на
декларацията



Каталожен номер	Название на продукта	Вид на устройството
GA-0006900	Lumenis Pulse 120H, INT 1PH	System
GA-0006800	Lumenis Pulse 120H, DOM 1PH	System
GA-0008800	Lumenis Pulse 120H, INT 3PH	System
GA-0006801	Lumenis Pulse 120H, DOM 1PH with Moses	System
RG-0006801	Lumenis Pulse 120H, DOM 1PH with Moses, Refurbished	System
GA-2003477	Lumenis Pulse 120H, INT 1PH No Suction	System
GA-2003476	Lumenis Pulse 120H, DOM 1PH No suction	System
GA-0008700	Lumenis Pulse 120H, INT 1PH 32A	System
GA-0006900CN	Lumenis Pulse 120H, 1PH, China	System
RG-0006900	Lumenis Pulse 120H, INT, 1PH, Refurbished	System
RG-0008800	Lumenis Pulse 120H, INT, 3PH, Refurbished	System
RG-0006800	Lumenis Pulse 120H, DOM 1PH, Refurbished	System
GA-2009996	Lumenis Pulse 120H, DOM 1 PH 30A	System
GA-0006902	Lumenis Pulse 120H, MOSES 2.0 (INT)	System
GA-0006802	Lumenis Pulse 120H, MOSES 2.0 (DOM)	System



Izjava o sukladnosti

Direktiva 2014/53/EU

DoC-1015589

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:

Lumenis Pulse 120H (LT-LFS03-SYS-05, LM940)

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 EN 62311
Članak 3.1b (Elektromagnetska kompatibilnost)	EN 60601-1-2 EN 301 489-1 EN 301 489-3 EN 301 489-52
Članak 3.2 (Spektar)	EN 300 330

Dan O' Callaghan (Director QA/QA)

Ime i prezime, potpredsjednik, Regulatorni poslovi i kvaliteta

Signing for VP

23 May 2022

Datum

Datum valjanosti izjave

Dudi Reznick (Director R&D)

Ime i prezime, potpredsjednik, Istraživanje i razvoj

Signing for VP

30 May 2022

Datum

Datum valjanosti izjave



Kataloški broj (HR)	Naziv proizvoda (HR)	Vrsta uređaja (HR)
GA-0006900	Lumenis Pulse 120H, INT 1PH	System
GA-0006800	Lumenis Pulse 120H, DOM 1PH	System
GA-0008800	Lumenis Pulse 120H, INT 3PH	System
GA-0006801	Lumenis Pulse 120H, DOM 1PH with Moses	System
RG-0006801	Lumenis Pulse 120H, DOM 1PH with Moses, Refurbished	System
GA-2003477	Lumenis Pulse 120H, INT 1PH No Suction	System
GA-2003476	Lumenis Pulse 120H, DOM 1PH No suction	System
GA-0008700	Lumenis Pulse 120H, INT 1PH 32A	System
GA-0006900CN	Lumenis Pulse 120H, 1PH, China	System
RG-0006900	Lumenis Pulse 120H, INT, 1PH, Refurbished	System
RG-0008800	Lumenis Pulse 120H, INT, 3PH, Refurbished	System
RG-0006800	Lumenis Pulse 120H, DOM 1PH, Refurbished	System
GA-2009996	Lumenis Pulse 120H, DOM 1 PH 30A	System
GA-0006902	Lumenis Pulse 120H, MOSES 2.0 (INT)	System
GA-0006802	Lumenis Pulse 120H, MOSES 2.0 (DOM)	System



Declarație de Conformitate

Directiva 2014/53/UE
DoC-1015589

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:

Lumenis Pulse 120H (LT-LFS03-SYS-05, LM940)

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 EN 62311
Articol 3.1b (Compatibilitate electromagnetica)	EN 60601-1-2 EN 301 489-1 EN 301 489-3 EN 301 489-52
Articol 3.2 (Spectru)	EN 300 330

Dan O'Callaghan (Director QA/QA) 23/ May/2022
Nume, VP, Afaceri de reglementare și Calitate Data

Signing for VP

Data de valabilitate a declarației

Dudi Reznick (Director R.D.) 30/ May/2022
Nume, VP, Cercetare și Dezvoltare Data

Signing for VP

Data de valabilitate a declarației



Număr de catalog	Denumire produs	Tipul dispozitivului
GA-0006900	Lumenis Pulse 120H, INT 1PH	System
GA-0006800	Lumenis Pulse 120H, DOM 1PH	System
GA-0008800	Lumenis Pulse 120H, INT 3PH	System
GA-0006801	Lumenis Pulse 120H, DOM 1PH with Moses	System
RG-0006801	Lumenis Pulse 120H, DOM 1PH with Moses, Refurbished	System
GA-2003477	Lumenis Pulse 120H, INT 1PH No Suction	System
GA-2003476	Lumenis Pulse 120H, DOM 1PH No suction	System
GA-0008700	Lumenis Pulse 120H, INT 1PH 32A	System
GA-0006900CN	Lumenis Pulse 120H, 1PH, China	System
RG-0006900	Lumenis Pulse 120H, INT, 1PH, Refurbished	System
RG-0008800	Lumenis Pulse 120H, INT, 3PH, Refurbished	System
RG-0006800	Lumenis Pulse 120H, DOM 1PH, Refurbished	System
GA-2009996	Lumenis Pulse 120H, DOM 1 PH 30A	System
GA-0006902	Lumenis Pulse 120H, MOSES 2.0 (INT)	System
GA-0006802	Lumenis Pulse 120H, MOSES 2.0 (DOM)	System



Uygunluk Beyanı

2014/53/AB Direktifi
DoC-1015589

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:

Lumenis Pulse 120H (LT-LFS03-SYS-05, LM940)

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 EN 62311
Madde 3.1b (Elektromanyetik uyumluluk)	EN 60601-1-2 EN 301 489-1 EN 301 489-3 EN 301 489-52
Madde 3.2 (Spektrum)	EN 300 330

Dan O'Callaghan (Director QA/QA)
İsim, Vice President - Başkan Yardımcısı,
Ruhsatlandırma ve Kalite

23/ May/2022

Tarih

Signing for VP

Beyanın Geçerlilik Tarihi

Dudi Reznick (Director R&D)
İsim, Vice President - Başkan Yardımcısı,
Araştırma ve Geliştirme

30/ May/2022

Tarih

Signing for VP

Beyanın Geçerlilik Tarihi



Katalog Numarası	Ürün Adı	Cihaz Tipi
GA-0006900	Lumenis Pulse 120H, INT 1PH	System
GA-0006800	Lumenis Pulse 120H, DOM 1PH	System
GA-0008800	Lumenis Pulse 120H, INT 3PH	System
GA-0006801	Lumenis Pulse 120H, DOM 1PH with Moses	System
RG-0006801	Lumenis Pulse 120H, DOM 1PH with Moses, Refurbished	System
GA-2003477	Lumenis Pulse 120H, INT 1PH No Suction	System
GA-2003476	Lumenis Pulse 120H, DOM 1PH No suction	System
GA-0008700	Lumenis Pulse 120H, INT 1PH 32A	System
GA-0006900CN	Lumenis Pulse 120H, 1PH, China	System
RG-0006900	Lumenis Pulse 120H, INT, 1PH, Refurbished	System
RG-0008800	Lumenis Pulse 120H, INT, 3PH, Refurbished	System
RG-0006800	Lumenis Pulse 120H, DOM 1PH, Refurbished	System
GA-2009996	Lumenis Pulse 120H, DOM 1 PH 30A	System
GA-0006902	Lumenis Pulse 120H, MOSES 2.0 (INT)	System
GA-0006802	Lumenis Pulse 120H, MOSES 2.0 (DOM)	System



Izjava o skladnosti

Direktiva 2014/53/EU
DoC-1015589

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:

Lumenis Pulse 120H (LT-LFS03-SYS-05, LM940)

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 EN 62311
Članek 3.1b (Elektromagnetna združljivost)	EN 60601-1-2 EN 301 489-1 EN 301 489-3 EN 301 489-52
Članek 3.2 (Spekter)	EN 300 330

Dean O'Callaghan (Director QA/RA)
Ime, podpredsednik, oddelek za regulativne
zadeve in kakovost

Signing for VP

23 / May / 2022

Datum

Datum veljavnosti izjave

Dudi Reznick (Director R&D)
Ime, podpredsednik, oddelek za raziskave
in razvoj

Signing for VP

30 / May / 2022

Datum

Datum veljavnosti izjave



Kataloška številka	Ime izdelka	Vrsta pripomočka
GA-0006900	Lumenis Pulse 120H, INT 1PH	System
GA-0006800	Lumenis Pulse 120H, DOM 1PH	System
GA-0008800	Lumenis Pulse 120H, INT 3PH	System
GA-0006801	Lumenis Pulse 120H, DOM 1PH with Moses	System
RG-0006801	Lumenis Pulse 120H, DOM 1PH with Moses, Refurbished	System
GA-2003477	Lumenis Pulse 120H, INT 1PH No Suction	System
GA-2003476	Lumenis Pulse 120H, DOM 1PH No suction	System
GA-0008700	Lumenis Pulse 120H, INT 1PH 32A	System
GA-0006900CN	Lumenis Pulse 120H, 1PH, China	System
RG-0006900	Lumenis Pulse 120H, INT, 1PH, Refurbished	System
RG-0008800	Lumenis Pulse 120H, INT, 3PH, Refurbished	System
RG-0006800	Lumenis Pulse 120H, DOM 1PH, Refurbished	System
GA-2009996	Lumenis Pulse 120H, DOM 1 PH 30A	System
GA-0006902	Lumenis Pulse 120H, MOSES 2.0 (INT)	System
GA-0006802	Lumenis Pulse 120H, MOSES 2.0 (DOM)	System



Vastavusdeklaratsioon

Direktiiv 2014/53/EL
DoC-1015589

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:

Lumenis Pulse 120H (LT-LFS03-SYS-05, LM940)

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 EN 62311
Artikkel 3.1b (Elektromagnetiline ühilduvus)	EN 60601-1-2 EN 301 489-1 EN 301 489-3 EN 301 489-52
Artikkel 3.2 (Spekter)	EN 300 330

Dan O'Callaghan (Director QA/QA)
Nimi, asepresident regulatiivküsimuste ja
kvaliteedi alal

Signing for VP

23 May 2022
Kuupäev

Deklaratsiooni kehtivuskuupäev

Rudi Ruznick (Director RnD)
Nimi, asepresident teaduse ja arenduse alal

Signing for VP

30 May 2022
Kuupäev

Deklaratsiooni kehtivuskuupäev



Katalooginumber	Toote nimi	Seadme tüüp
GA-0006900	Lumenis Pulse 120H, INT 1PH	System
GA-0006800	Lumenis Pulse 120H, DOM 1PH	System
GA-0008800	Lumenis Pulse 120H, INT 3PH	System
GA-0006801	Lumenis Pulse 120H, DOM 1PH with Moses	System
RG-0006801	Lumenis Pulse 120H, DOM 1PH with Moses, Refurbished	System
GA-2003477	Lumenis Pulse 120H, INT 1PH No Suction	System
GA-2003476	Lumenis Pulse 120H, DOM 1PH No suction	System
GA-0008700	Lumenis Pulse 120H, INT 1PH 32A	System
GA-0006900CN	Lumenis Pulse 120H, 1PH, China	System
RG-0006900	Lumenis Pulse 120H, INT, 1PH, Refurbished	System
RG-0008800	Lumenis Pulse 120H, INT, 3PH, Refurbished	System
RG-0006800	Lumenis Pulse 120H, DOM 1PH, Refurbished	System
GA-2009996	Lumenis Pulse 120H, DOM 1 PH 30A	System
GA-0006902	Lumenis Pulse 120H, MOSES 2.0 (INT)	System
GA-0006802	Lumenis Pulse 120H, MOSES 2.0 (DOM)	System



Atbilstības Deklarācija

Direktīva 2014/53/ES
DoC-1015589

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:

Lumenis Pulse 120H (LT-LFS03-SYS-05, LM940)

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 EN 62311
3.1.b punkts (Elektromagnētiskā saderība)	EN 60601-1-2 EN 301 489-1 EN 301 489-3 EN 301 489-52
3.2. punkts (Spektrs)	EN 300 330

Don O' Callaghan (Director QA/QA)
Vārds, viceprezidents, regulatīvie jautājumi
un kvalitāte

Signing for VP

23 May 2022
Datums

Deklarācijas spēkā stāšanās
datums

Dudi Reznick (Director RnD)
Vārds, viceprezidents, izpēte un attīstība
Signing for VP

30 May 2022
Datums

Deklarācijas spēkā stāšanās
datums



Izstrādājuma nosaukums	Kataloga numurs	Ierīces veids
GA-0006900	Lumenis Pulse 120H, INT 1PH	System
GA-0006800	Lumenis Pulse 120H, DOM 1PH	System
GA-0008800	Lumenis Pulse 120H, INT 3PH	System
GA-0006801	Lumenis Pulse 120H, DOM 1PH with Moses	System
RG-0006801	Lumenis Pulse 120H, DOM 1PH with Moses, Refurbished	System
GA-2003477	Lumenis Pulse 120H, INT 1PH No Suction	System
GA-2003476	Lumenis Pulse 120H, DOM 1PH No suction	System
GA-0008700	Lumenis Pulse 120H, INT 1PH 32A	System
GA-0006900CN	Lumenis Pulse 120H, 1PH, China	System
RG-0006900	Lumenis Pulse 120H, INT, 1PH, Refurbished	System
RG-0008800	Lumenis Pulse 120H, INT, 3PH, Refurbished	System
RG-0006800	Lumenis Pulse 120H, DOM 1PH, Refurbished	System
GA-2009996	Lumenis Pulse 120H, DOM 1 PH 30A	System
GA-0006902	Lumenis Pulse 120H, MOSES 2.0 (INT)	System
GA-0006802	Lumenis Pulse 120H, MOSES 2.0 (DOM)	System



Atitikties Deklaracija

Direktyva 2014/53/ES
DoC-1015589

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

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

Lumenis Pulse 120H (LT-LFS03-SYS-05, LM940)

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 EN 62311
Straipsnis 3.1b (Elektromagnetinis suderinamumas)	EN 60601-1-2 EN 301 489-1 EN 301 489-3 EN 301 489-52
Straipsnis 3.2 (Spektras)	EN 300 330

Dan O' Callaghan (Director QA/QA)

Vardas ir pavardė, viceprezidentas (-ė),
Reglamentavimo reikalai ir kokybė

Signing for VP

23/May/2022

Data

Deklaracijos galiojimo data

Dudi Reznick (Director R&D)

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

Signing for VP

30/May/2022

Data

Deklaracijos galiojimo data



Katalogo numeris	Gaminio pavadinimas	Prietaiso tipas
GA-0006900	Lumenis Pulse 120H, INT 1PH	System
GA-0006800	Lumenis Pulse 120H, DOM 1PH	System
GA-0008800	Lumenis Pulse 120H, INT 3PH	System
GA-0006801	Lumenis Pulse 120H, DOM 1PH with Moses	System
RG-0006801	Lumenis Pulse 120H, DOM 1PH with Moses, Refurbished	System
GA-2003477	Lumenis Pulse 120H, INT 1PH No Suction	System
GA-2003476	Lumenis Pulse 120H, DOM 1PH No suction	System
GA-0008700	Lumenis Pulse 120H, INT 1PH 32A	System
GA-0006900CN	Lumenis Pulse 120H, 1PH, China	System
RG-0006900	Lumenis Pulse 120H, INT, 1PH, Refurbished	System
RG-0008800	Lumenis Pulse 120H, INT, 3PH, Refurbished	System
RG-0006800	Lumenis Pulse 120H, DOM 1PH, Refurbished	System
GA-2009996	Lumenis Pulse 120H, DOM 1 PH 30A	System
GA-0006902	Lumenis Pulse 120H, MOSES 2.0 (INT)	System
GA-0006802	Lumenis Pulse 120H, MOSES 2.0 (DOM)	System



Samræmisyfirlýsing

Tilskipun 2014/53/ESB
DoC-1015589

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 samhæfingarlöggjöf Sambandsins sem kveður á um tilskipun 2014/53/ESB:

Lumenis Pulse 120H (LT-LFS03-SYS-05, LM940)

Viðeigandi samhæfðir staðlar og/eða tækniforskriftir sem notaðar eru í tengslum við þessa samræmisyfirlýsingu eru:

Tilskipun 2014/53/ESB	Staðlar
Gr 3.1a (Öryggi)	EN 60601-1 EN 50364 EN 62311
Gr 3.1b (Rafsegulsamhæfni)	EN 60601-1-2 EN 301 489-1 EN 301 489-3 EN 301 489-52
Gr 3.2 (Litróf)	EN 300 330

Don O'Callaghan (Director QA/RA)
Nafn, varaforseti, reglu- og gæðamál

Signing for VP

23 May 2022
Dagsetning

Gildisdagur
samræmisyfirlýsingar

Avdi Beznick (Director RnD)
Nafn, varaforseti, rannsóknir og þróun
Signing for VP

30 May 2022
Dagsetning

Gildisdagur
samræmisyfirlýsingar



Vörulista-Númer	Vöruheiti	Tegund búnaðar
GA-0006900	Lumenis Pulse 120H, INT 1PH	System
GA-0006800	Lumenis Pulse 120H, DOM 1PH	System
GA-0008800	Lumenis Pulse 120H, INT 3PH	System
GA-0006801	Lumenis Pulse 120H, DOM 1PH with Moses	System
RG-0006801	Lumenis Pulse 120H, DOM 1PH with Moses, Refurbished	System
GA-2003477	Lumenis Pulse 120H, INT 1PH No Suction	System
GA-2003476	Lumenis Pulse 120H, DOM 1PH No suction	System
GA-0008700	Lumenis Pulse 120H, INT 1PH 32A	System
GA-0006900CN	Lumenis Pulse 120H, 1PH, China	System
RG-0006900	Lumenis Pulse 120H, INT, 1PH, Refurbished	System
RG-0008800	Lumenis Pulse 120H, INT, 3PH, Refurbished	System
RG-0006800	Lumenis Pulse 120H, DOM 1PH, Refurbished	System
GA-2009996	Lumenis Pulse 120H, DOM 1 PH 30A	System
GA-0006902	Lumenis Pulse 120H, MOSES 2.0 (INT)	System
GA-0006802	Lumenis Pulse 120H, MOSES 2.0 (DOM)	System