



PEMERINTAH REPUBLIK INDONESIA

PERIZINAN BERUSAHA UNTUK MENUNJANG KEGIATAN USAHA IZIN EDAR ALAT KESEHATAN IMPOR PB-UMKU: 912040398089700010009

Pemerintah Republik Indonesia menerbitkan Perizinan Berusaha Untuk Menunjang Kegiatan Usaha (PB-UMKU), yang merupakan Izin edar alat kesehatan impor kepada Pelaku Usaha berikut ini:

- | | |
|--|---|
| 1. Nama Pelaku Usaha | : PT SINERGI MEDIKA UTAMA |
| 2. Nomor Induk Berusaha (NIB) | : 9120403980897 |
| 3. Alamat Kantor | : Komplek Taman Palem Lestari Blok P No. 3 Lantai 3 , Desa/Kelurahan Cengkareng Barat, Kec. Cengkareng, Kota Adm. Jakarta Barat, Provinsi DKI Jakarta
Kode Pos: 11730 |
| 4. Status Penanaman Modal | : Penanaman Modal Dalam Negeri (PMDN) |
| 5. Kode Klasifikasi Baku Lapangan Usaha Indonesia (KBLI) | : 46691 - Perdagangan Besar Alat Laboratorium, Alat Farmasi Dan Alat Kedokteran Untuk Manusia |
| 6. Lokasi Usaha | : Komplek Taman Palem Lestari Blok P No.3 Lt.3 RT.013 RW.008 Kel. Cengkareng Barat, Kec. Cengkareng, Jakarta Barat, DKI Jakarta
Desa/Kelurahan Cengkareng Barat, Kec. Cengkareng, Kota Adm. Jakarta Barat, Provinsi DKI Jakarta
Kode Pos: 11730 |

Telah memenuhi persyaratan:

1. Persyaratan Administrasi
2. Persyaratan Teknis dan

Lampiran Perizinan Berusaha Untuk Menunjang Kegiatan Usaha ini memuat data teknis yang merupakan bagian tidak terpisahkan dari dokumen ini. Pelaku Usaha tersebut di atas wajib menjalankan kegiatan usahanya sesuai dengan ketentuan perundang-undangan yang berlaku.

Diterbitkan tanggal: 22 April 2023

Perubahan ke-1, tanggal:

**a.n. Menteri Kesehatan
Menteri Investasi/
Kepala Badan Koordinasi Penanaman Modal,**



Ditandatangani secara elektronik

Dicetak tanggal: 26 April 2023

1. Dokumen ini diterbitkan sistem OSS berdasarkan data dari Pelaku Usaha, tersimpan dalam sistem OSS, yang menjadi tanggung jawab Pelaku Usaha.
2. Dalam hal terjadi kekeliruan isi dokumen ini akan dilakukan perbaikan sebagaimana mestinya.
3. Dokumen ini telah ditandatangani secara elektronik menggunakan sertifikat elektronik yang diterbitkan oleh BSR-E-BSSN.
4. Data lengkap Perizinan Berusaha dapat diperoleh melalui sistem OSS menggunakan hak akses.





PEMERINTAH REPUBLIK INDONESIA

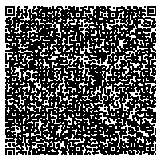
**PERIZINAN BERUSAHA UNTUK MENUNJANG KEGIATAN USAHA
LAMPIRAN
IZIN EDAR ALAT KESEHATAN IMPOR
PB-UMKU : 912040398089700010009**

Lampiran berikut memuat data teknis Izin Edar Alat Kesehatan Impor, sebagai berikut:

KEMENKES RI AKL 21002320131

Nama Dagang / Merek : **VISAR Stereotaxic Instrument System**
Kelompok / Kelas Resiko : Elektromedik Non Radiasi / B
Kategori Produk : Peralatan Neurologi
Sub Kategori : Peralatan Neurologi Bedah
Jenis Produk : Stereotaxic instrument.
Tipe / Ukuran : 53mm to 71mm inclusive
Kemasan : Peking Kayu
Nama Produsen / Pabrikasi : NOVARAD CORPORATION, United States
Atas dasar lisensi dari : -
Ketentuan

1. Persetujuan izin edar berlaku sampai dengan 05 Desember 2027.
2. Wajib menyampaikan laporan berkala dan laporan jika ada kejadian yang tidak diinginkan akibat penggunaan Alat Kesehatan tersebut di atas sesuai ketentuan berlaku.
3. Apabila dikemudian hari ada pihak lain yang berhak atas merek dan/atau keagenan produk tersebut, pendaftar bersedia mengembalikan izin edar .
4. Penandaan dan informasi produk yang terlampir merupakan bagian yang tidak terpisahkan dari persetujuan izin edar ini.
5. Apabila di kemudian hari terdapat kekeliruan, maka persetujuan izin edar ini akan ditinjau kembali.



1. Dokumen ini diterbitkan sistem OSS berdasarkan data dari Pelaku Usaha, tersimpan dalam sistem OSS, yang menjadi tanggung jawab Pelaku Usaha.
2. Dalam hal terjadi kekeliruan isi dokumen ini akan dilakukan perbaikan sebagaimana mestinya.
3. Dokumen ini telah ditandatangani secara elektronik menggunakan sertifikat elektronik yang diterbitkan oleh BSR-E-BSSN.
4. Data lengkap Perizinan Berusaha dapat diperoleh melalui sistem OSS menggunakan hak akses.



**Balai
Sertifikasi
Elektronik**



Quality System Procedure (QSP)

Document Number:

QSP 7.5.1

Revision:

3.0

Date:

06/01/2022

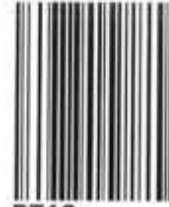
Requirements for Labeling and Packaging

Small vertical text on the left margin, likely a copyright or disclaimer notice.

NRSERVER04



NRSERVER04 -



R710 -

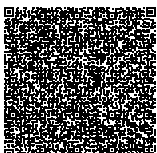


Edgebrook Radiology

Edgebrook Radiology

Didistribusikan Oleh:
PT. Sinergi Medika Utama
Jakarta-Indonesia

Kemenkes RI AKL:





Quality System Procedure (QSP)

Document Number:

QSP 7.5.1

Revision:

3.0

Date:

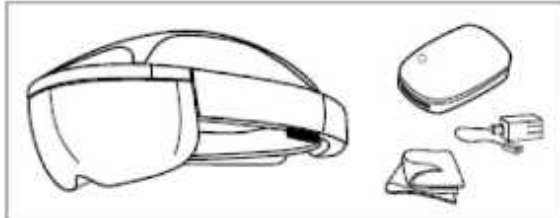
06/01/2022

Requirements for Labeling and Packaging



566 grams

Package Includes:
HoloLens 2 Device
Carrying Case
Overhead Strap
Microfiber Cloth
Charger
USB-C Cable
Novarad VisAR Software



2020-12-17

Qty: 1 Unit



Keep Dry

Rx ONLY



Storage Temperature



Transport Temperature



Transport & Storage Humidity Limits



Transport & Storage Barometric Pressure Limits



Has not been subjected to a sanitization process



Consult instructions for use for cleaning instructions



Do not use if package is damaged



Caution: Consult instructions for use



Do not throw in trash



www.novarad.net



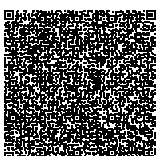
Distributed By:
Novarad, 3152 N. University Avenue, Provo, UT
84604, U.S.A. Customer Service 1-877-668-2723



Emergo Group / Emergo Europe
Prinsessegracht 20, 2514 AP The Hague,
The Netherlands
Tel.: (31) (0) 70 345-8570
Fax: (31) (0) 70 346-7299

Didistribusikan Oleh:
PT. Sinergi Medika Utama
Jakarta-Indonesia

Kemenkes RI AKL:





Quality System Procedure (QSP)

Document Number:

QSP 7.5.1

Revision:


3.0

Date:


06/01/2022

Requirements for Labeling and Packaging

ARTag shipping label example:



REF 1,8805-1



Qty: 1 Unit
Containing 5 Tags

STERILE

R

⏳ YYYY-MM-DD

②

⚠️

⚠️

Rx ONLY

LOT XXXXXXX

📅 YYYY-MM-DD


☔

🚫

🚫


💡


www.novarad.net



REF 1,8805-1

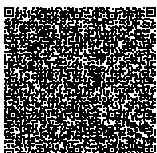
LOT XXXXXXX

 **Manufactured By:**
Novarad, 3152 N. University Avenue, Provo, UT 84604, U.S.A.
Customer Service 1-877-668-2723
www.novarad.net

 **EC REP** Emergo Group / Emergo Europe
Prinsessegracht 20, 2514 AP The Hague, The Netherlands
Tel.: (31) (0) 70 345-8570
Fax: (31) (0) 70 346-7299

Didistribusikan Oleh:
PT. Sinergi Medika Utama
Jakarta-Indonesia

Kemenkes RI AKL:





Quality System Procedure (QSP)

Document Number:
QSP 7.5.1

Revision:
3.0

Date:
06/01/2022

Requirements for Labeling and Packaging

Needle Stop Set shipping label example:



REF 1.8805-4



Qty: 2 Needle
Stops per Package
(1 Large & 1 Small)

STERILE

R

YYYY-MM-DD

②

WPC

!

Rx ONLY

LOT XXXXXXX

YYYY-MM-DD

☂

☞

☞

☞

www.novarad.net


REF 1.8805-4
LOT XXXXXXX

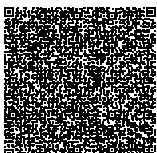

7 53459 66897 9

 **Manufactured By:**
Novarad, 3152 N. University Avenue, Provo, UT 84604, U.S.A.
Customer Service 1-877-668-2723
www.novarad.net

EC/REP Emergo Group / Emergo Europe
Prinsessegracht 20, 2514 AP The Hague, The Netherlands
Tel.: (31) (0) 70 345-8570
Fax: (31) (0) 70 346-7299

Didistribusikan Oleh:
PT. Sinergi Medika Utama
Jakarta-Indonesia

Kemenkes RI AKL:





Quality System Procedure (QSP)

Document Number:

QSP 7.5.1

Revision:

3.0

Date:

06/01/2022

Requirements for Labeling and Packaging

Tag Mount Kit (Offset) shipping label example:

VisAR

Tag Mount Kit (Offset)

REF

1.8805-3

Qty: 3 Tag Mounts (90° Angle)
with Set Screw

STERILE	R	YYYY-MM-DD	②	100% STERILE	! R _x ONLY
LOT	XXXXXXX	YYYY-MM-DD	☂	☞	☞

www.novarad.net

NOVARAD
ENTERPRISE IMAGING SOLUTIONS

REF

 1.8805-3

7 53459 63609 1

LOT

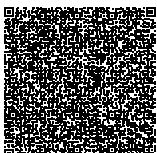
 XXXXXXX

Manufactured By:
Novarad, 3152 N. University Avenue, Provo, UT 84604, U.S.A.
Customer Service 1-877-668-2723
www.novarad.net

EC REP: Emergo Group / Emergo Europe
Prinsessegracht 20, 2514 AP The Hague, The Netherlands
Tel.: (31) (0) 70 345-8570
Fax: (31) (0) 70 346-7299

Didistribusikan Oleh:
PT. Sinergi Medika Utama
Jakarta-Indonesia

Kemenkes RI AKL:





Quality System Procedure (QSP)

Document Number:

QSP 7.5.1

Revision:

3.0

Date:

06/01/2022

Requirements for Labeling and Packaging

Tag Mount Kit (Center) shipping label example:

VisARTag Mount Kit (Center)

REF 1.8805-2

Qty: 3 Tag Mounts
with Set Screw

STERILE	R	YYYY-MM-DD	2	rec	!	Rx ONLY
LOT	XXXXXXX	YYYY-MM-DD	☔	⊘	⊘	💡

www.novarad.net

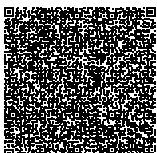
REF 1.8805-2

LOT XXXXXXX

Manufactured By:
Novarad, 3152 N. University Avenue, Provo, UT 84604, U.S.A.
Customer Service 1-877-668-2723
www.novarad.net

EC REP Emergo Group / Emergo Europe
Prinsessegracht 20, 2514 AP The Hague, The Netherlands
Tel.: (31) (0) 70 345-8570
Fax: (31) (0) 70 346-7299

Didistribusikan Oleh:
PT. Sinergi Medika Utama
Jakarta-IndonesiaKemenkes RI AKL:





Quality System Procedure (QSP)

Document Number:
QSP 7.5.1

Revision:
3.0

Date:
06/01/2022

Design Packaging

ARTag packaging example:



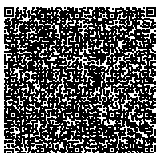
Needle Stop Set packaging example:

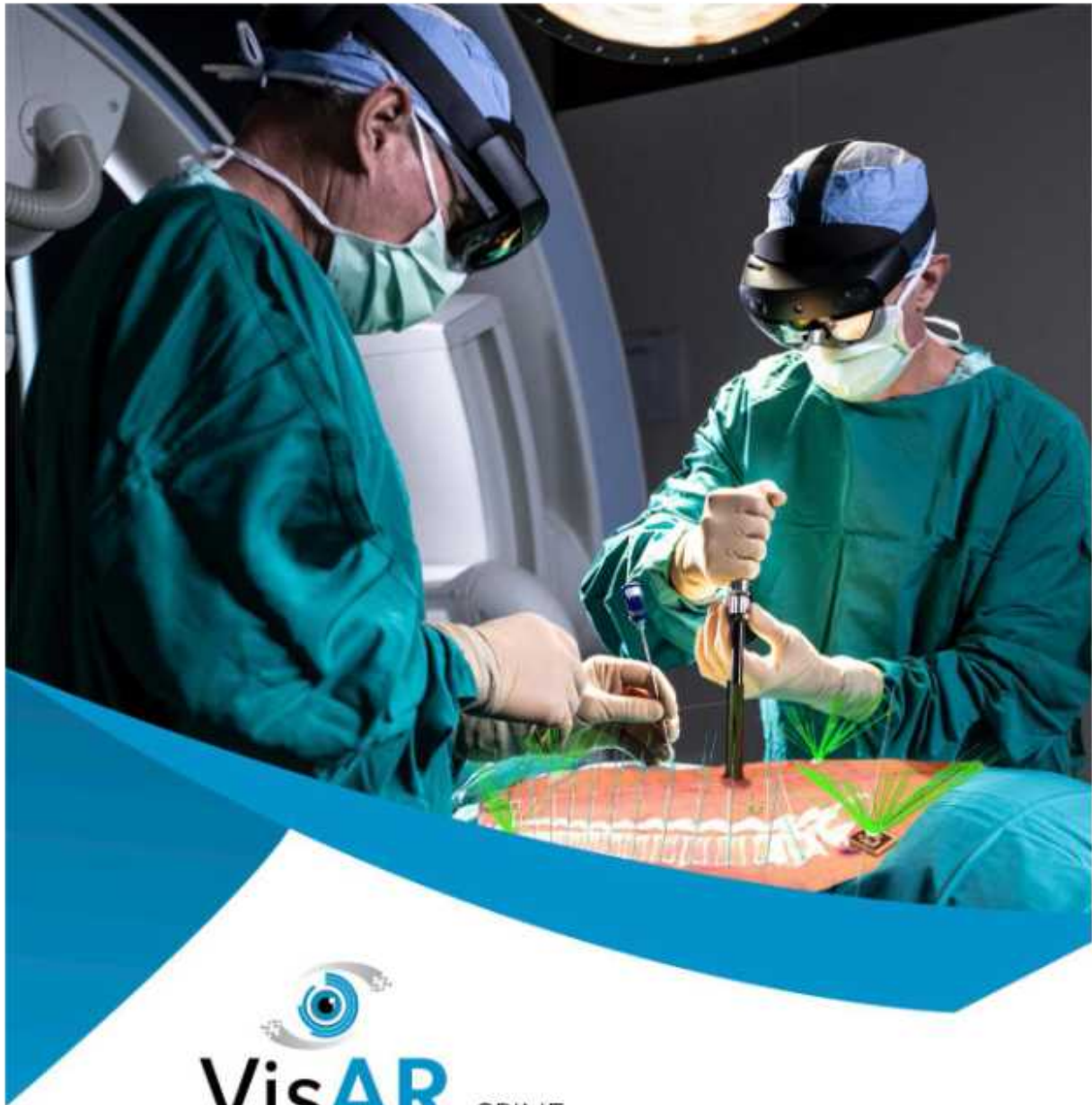


Tag Mount Kit (Offset) packaging example:



Tag Mount Kit (Center) packaging example:

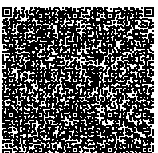





VisAR SPINE

TRANSFORMATIVE AUGMENTED REALITY
SURGICAL GUIDANCE SYSTEM

 **NOVARAD**
NOVARAD CORPORATION



PRECISION HEALTHCARE



VisAR significantly improves my precision in the operating room. Specifically, it allows me to determine exactly where to place my incision thereby allowing me to keep the incision small—minimizing pain and also shortens my operative time by allowing me to expose the surgical target more precisely and quickly.

Dr. Babak Sarani

Director of Trauma and Acute Care Surgery at the GW Hospital.

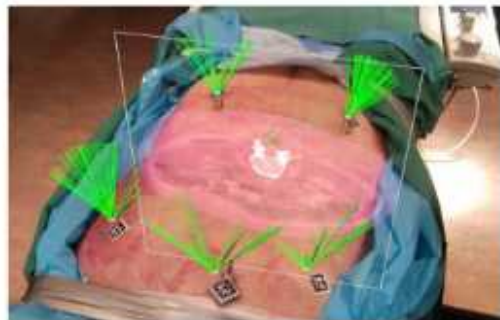
ADVANCED RENDERING

VisAR renders 2D and 3D digital images from any modality into a highly detailed projection in real-time using the Novarad Graphics Engine. Using patented virtual tool technology with an integrated targeting system, the projection is overlaid directly and precisely onto a patient's body.



PRECISE REGISTRATION

- Optical tags
- Precise registration
- Free-hand
- Continuous registration
- Registration status indicator



INTEGRATED VIRTUAL TARGETING SYSTEM

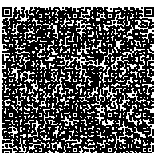
- Virtual tools, guide
- Dynamic alignment
- Virtual distance read-out
- Reticle for precise alignment



MINIMAL OPERATIVE FOOTPRINT

Using optical code alignment, cameras, and sensors, VisAR maps both the patient and the surrounding environment. Using the hands-free, untethered HoloLens 2 stereogenic navigation is performed.

Novarad® VisAR is an augmented reality surgical guidance system where the entire operating room footprint is on the surgeon's head.



ADVANCED PREOPERATIVE PLANNING

* Operative 510(k) clearance pending

- Colorize target organs or annotate pathology to create semitransparent projections of targeted anatomy. This allows for planning and execution of the procedure, even around difficult anatomy.
- Place virtual incisions on the projected images for precise surgery.
- Navigate with precision. Mark virtual surgical guide entrance point, trajectory and location for endoscope or needle placement, or placement of a pedicle screw. Procedures can be done both under open surgery and percutaneously.

VisAR ADVANTAGES

	Traditional Navigation Systems	VisAR	VisAR Advantage
Size	Large, cumbersome system that requires a monitor	Simple, untethered headset, no monitor required	Easier to use Smaller IT footprint
Cost	Often more than \$1.5 M	\$60K - \$300K set up \$5K monthly fee	Costs significantly less
Set up time	At least 45 minutes	2 minutes, no need for line of sight to instruments from IR transmitter	Less time in OR, less time patient is under anesthesia
Mobility	Limited utility, one patient at a time	Can be used in multiple ORs and departments simultaneously	Faster ROI
Versatility	Often sits unused	Can be used by Neuro, Ortho, Interventional Radiology, etc.	Cost spread across many uses
Scalability	1	Dozens	Easy to expand use

VisAR LEADS THE MARKET

- Predecessor technology (OpenSight®) was first AR surgical system to receive FDA clearance using Microsoft HoloLens
- Advanced 3D rendering without tethering
- Advanced 3D image segmentation
- Patented or patent pending innovations
 - Optical Tag Registration
 - Surface Shell Registration
 - Virtual tools for incision, markers, needles, trocars and more
 - Viewing AR images in a 3D volume over patient
 - Optical encoding of login, password and image retrieval
 - Virtual Annotations
- Anatomic labeling, pathologic markup
- Dynamic virtual targeting system for tracking lesions and trocar placement
- Enterprise Imaging, HIPAA logging, LDAP logins, data encryption, auto-routing



VisAR LEADS THE MARKET
WITH MANY FIRSTS



*WIP: Work in Progress. Not 510(k) cleared.

Learn more | Download the VisAR demo at the Microsoft App store at <https://www.microsoft.com/en-us/p/visar/9nh2399k92jw>



CORPORATE HEADQUARTERS

3152 N University Ave, Suite 250
Provo, Utah 84604
(877) 668-2723

UNITED KINGDOM

12 Kingsbury Trading Estate Church Ln,
Kingsbury London United Kingdom
NW9 8AU
Phone: +44 (0) 208 205 9500
Fax: +44 (0) 208 205 0585

LATIN AMERICA

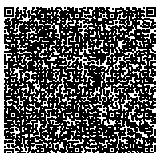
2 Calle A 6-28 zona 10 Edificio
Verona, Oficina 502
Edificio Verona, Oficina 502
Guatemala, Guatemala

ASIA PACIFIC

12 Emerald Ave
San Antonio, Pasig, 1605
Metro Manila, Philippines



* Intel, the Intel logo, and other Intel marks are trademarks of Intel Corporation or its subsidiaries. © 2021 Novarad® Corporation. All rights reserved.
U.S. Patent Numbers: 9,892,564; 10,010,379; 10,475,344; 10,475,344; 10,825,563; 10,945,807; and 11,004,271. This device is not approved for sale in the United States.



PRODUCT IMAGE

PRECISION HEALTHCARE



VisAR significantly improves my precision in the operating room. Specifically, it allows me to determine exactly where to place my incision thereby allowing me to keep the incision small—minimizing pain and also shortens my operative time by allowing me to expose the surgical target more precisely and quickly.

Dr. Babak Sarani
Director of Trauma and Acute Care Surgery at the GW Hospital.

MINIMAL OPERATIVE FOOTPRINT

Using optical code alignment, cameras, and sensors, VisAR maps both the patient and the surrounding environment. Using the hands-free, untethered HoloLens 2 stereogenic navigation is performed.

Novarad® VisAR is an augmented reality surgical guidance system where the entire operating room footprint is on the surgeon's head.



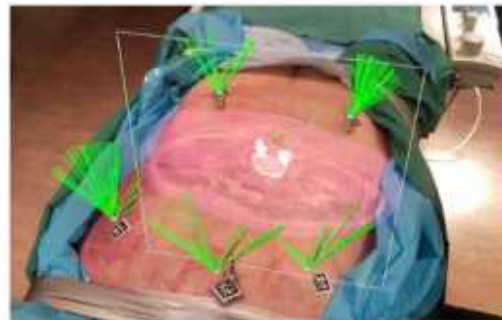
ADVANCED RENDERING

VisAR renders 2D and 3D digital images from any modality into a highly detailed projection in real-time using the Novarad Graphics Engine. Using patented virtual tool technology with an integrated targeting system, the projection is overlaid directly and precisely onto a patient's body.



PRECISE REGISTRATION

- Optical tags
- Precise registration
- Free-hand
- Continuous registration
- Registration status indicator



INTEGRATED VIRTUAL TARGETING SYSTEM

- Virtual tools, guide
- Dynamic alignment
- Virtual distance read-out
- Reticle for precise alignment

