



FICHA TÉCNICA DE NIPRO:
AGUJA HIPODÉRMICA

1. Referencia del producto

- Aguja hipodérmica con punta de lanceta y siliconización original que minimiza el dolor y el daño al paciente.
- Diseñada para maximizar el flujo del medicamento gracias a su pared FLOMAX.

Referencia	Diámetro de la aguja gauge (mm)	Longitud de la aguja pulgadas (mm)	Código de color ISO	Procedimiento
HN 1625 ET	16 G (1,6 mm)	1 " (25 mm)	Blanco	Transferencia
HN 1638 ET	16 G (1,6 mm)	1 1/2 " (40 mm)		
HN 1825 ET	18 G (1,2 mm)	1 " (25 mm)		
HN 1832 ET	18 G (1,2 mm)	1 1/4 " (30 mm)	Rosa	Transferencia
HN 1838 ET	18 G (1,2 mm)	1 1/2 " (40 mm)		
HN 1925 ET	19 G (1,1 mm)	1 " (25 mm)		
HN 1932 ET	19 G (1,1 mm)	1 1/4 " (30 mm)	Marfil	Intravenoso
HN 1938 ET	19 G (1,1 mm)	1 1/2 " (40 mm)		
HN 2025 ET	20 G (0,9 mm)	1 " (25 mm)		
HN 2038 ET	20 G (0,9 mm)	1 1/2 " (40mm)	Amarillo	Intravenoso
HN 2116 ET	21 G (0,8 mm)	5/8 " (16 mm)		
HN 2125 ET	21 G (0,8 mm)	1 " (25 mm)		
HN 2138 ET	21 G (0,8 mm)	1 1/2 " (40 mm)	Verde	Intramuscular
HN 2232 ET	22 G (0,7 mm)	1 1/4 " (30 mm)		
HN 2238 ET	22 G (0,7 mm)	1 1/2 " (40 mm)		
HN 2316 ET	23 G (0,6 mm)	5/8 " (16 mm)	Negro	Inyección intravenosa / Intramuscular
HN 2325 ET	23 G (0,6 mm)	1 " (25 mm)		
HN 2332 ET	23 G (0,6 mm)	1 1/4 " (30 mm)		
HN 2316 ET	23 G (0,6 mm)	5/8 " (16 mm)	Azul	Inyección intravenosa / Intramuscular
HN 2325 ET	23 G (0,6 mm)	1 " (25 mm)		
HN 2332 ET	23 G (0,6 mm)	1 1/4 " (30 mm)		
HN 2316 ET	23 G (0,6 mm)	5/8 " (16 mm)	Azul	Inyección intravenosa / Intramuscular
HN 2325 ET	23 G (0,6 mm)	1 " (25 mm)		
HN 2332 ET	23 G (0,6 mm)	1 1/4 " (30 mm)		
HN 2332 ET	23 G (0,6 mm)	1 1/4 " (30 mm)	Violeta	Inyección intravenosa / Intramuscular en niños
HN 2425 ET	24 G (0,55 mm)	1 " (25 mm)		
HN 2432 ET	24 G (0,55 mm)	1 1/4 " (30 mm)		
HN 2425 ET	24 G (0,55 mm)	1 " (25 mm)	Naranja	Subcutáneo
HN 2513 ET	25 G (0,5 mm)	1/2 " (13 mm)		
HN 2516 ET	25 G (0,5 mm)	5/8 " (16 mm)		
HN 2519 ET	25 G (0,5 mm)	3/4 " (19 mm)		
HN 2525 ET	25 G (0,5 mm)	1 " (25 mm)		
HN 2532 ET	25 G (0,5 mm)	1 1/4 " (30 mm)		
HN 2613 ET	26 G (0,45 mm)	1/2 " (13 mm)	Marrón	Subcutáneo / Intradérmico
HN 2622 ET	26 G (0,45 mm)	7/8 " (22 mm)		
HN 2713 ET	27 G (0,4 mm)	1/2 " (13 mm)	Gris	Subcutáneo / Intradérmico
HN 2719 ET	27 G (0,4 mm)	3/4 " (19 mm)		
HN 2732 ET	27 G (0,4 mm)	1 1/4 " (30 mm)		
HN 2738 ET	27 G (0,4 mm)	1 1/2 " (40 mm)		
HN 2913 ET	29 G (0,3 mm)	1/2 " (13 mm)		
HN 2913 ET	29 G (0,3 mm)	1/2 " (13 mm)	Rojo	Intradérmico

Observación: producto estándar, cánula biselada regular

2. Materiales

Todos los materiales utilizados para la producción de nuestras agujas hipodérmicas son aptos para uso médico y no contienen látex.

Nombre del componente	Material
Funda protectora de la aguja	Polipropileno
Conector de la aguja	Polipropileno
Cánula	Acero inoxidable SUS-304
Pegamento	Epoxi

La funda protectora de la aguja está disponible en dos tamaños: 38 mm y 54 mm. La funda protectora de 38 mm se utiliza habitualmente con agujas cuya longitud es igual o inferior a 25 mm (1").

La funda protectora de 54 mm puede utilizarse con todas las agujas, independientemente de su longitud.

3. Impresión

Los símbolos gráficos utilizados en el etiquetado de los productos sanitarios han sido diseñados de conformidad con lo dispuesto en la Norma BS EN 980:2003.

4.1 Información general relativa al embalaje

La esterilidad del producto queda garantizada por el embalaje individual y un indicador químico fijado en la caja exterior. Los envases individuales están realizados en papel estéril y película de PVC. La caja interior está realizada en cartón dúplex, mientras que la caja intermedia y la caja exterior están realizadas en cartón corrugado simple.

Todos los productos son envasados de conformidad con lo dispuesto en la norma BS EN 868-5/1999 relativa a los productos sanitarios que deban ser esterilizados.

Todas las unidades de embalaje contienen información sobre el número de lote, la vida útil y la esterilización del producto.

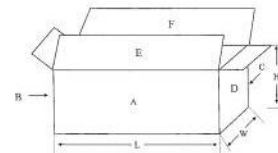
4.2 Tamaño del embalaje

→ Cada envase individual de tipo blíster contiene una aguja hipodérmica.

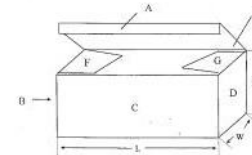
→ Cada tira de agujas consta de 5 unidades estériles envasadas individualmente.

Producto	Envase individual		Tira			Todas las medidas que se indican en las tablas siguientes están expresadas en mm
	Longitud	Anchura	Longitud	Anchura	Cantidad	
HN	83	20	83	100	5 uds	

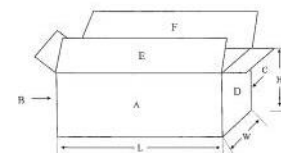
→ Una caja interior contiene 20 tiras de agujas estériles envasadas individualmente (100 unidades)



→ Una caja intermedia contiene 20 cajas interiores (2 000 unidades)



→ Una caja exterior contiene 5 cajas intermedias (10 000 unidades)



A. Agujas con una longitud igual o inferior a 1" (25 mm)

Producto	Caja interior				Caja intermedia				Caja exterior			
	Longitud	Anchura	Altura	Cantidad	Longitud	Anchura	Altura	Cantidad	Longitud	Anchura	Altura	Cantidad
HN	90	110	75	100 uds	473	311	126	2 000 uds	323	667	491	10 000 uds

B. Agujas con una longitud entre 1" (25 mm) y 2" (50 mm) – (excluidas las agujas de 1" y 2")

Producto	Caja interior				Caja intermedia				Caja exterior			
	Longitud	Anchura	Altura	Cantidad	Longitud	Anchura	Altura	Cantidad	Longitud	Anchura	Altura	Cantidad
HN	90	110	85	100 uds	473	353	126	2 000 uds	360	667	485	10 000 uds

5. Impresión del embalaje

Las etiquetas contienen el texto en 12 idiomas y su diseño es conforme a lo establecido en las especificaciones de la Directiva europea sobre productos sanitarios y la FDA.

Los idiomas son inglés, francés, holandés, alemán, español, italiano, portugués, griego, sueco, danés, noruego y finlandés.

6. Calidad

El producto cumple con lo dispuesto en la Directiva CD 93/42/EEC (MDD) y en la Norma ISO 13485:2003.

El producto cumple con lo dispuesto en la Norma ISO 7864:1993 relativa a las agujas hipodérmicas estériles de un solo uso.

El producto cumple con lo dispuesto en la Norma ISO 9626:1995/A1:2001 relativa al tubo de acero inoxidable para agujas utilizado en la fabricación de productos sanitarios.

Producto esterilizado con óxido de etileno



7. Características

Producto diseñado de conformidad con las normas armonizadas para garantizar una conexión perfecta con otros dispositivos, siempre que estos cumplan con las normas de armonización: EN-1707 y ANSI/HIMA MD 70.1.

La identificación por códigos de color se ha realizado de conformidad con lo dispuesto en la Norma ISO 6009:1992.

- Vida útil del producto: 5 años



- Un solo uso



Nipro Europe N.V.

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Bélgica

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www.nipro-europe.com

Your Partner in Safety and Quality



Benannt durch/Designated by
 Zentralstelle der Länder
 für Gesundheitsschutz
 bei Arzneimitteln und
 Medizinprodukten
 www.zlg.de
 ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System
 Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
 (Devices in Class IIa, IIb or III)

No. G1 043398 0279 Rev. 01

Manufacturer: **Nipro Corporation**
 3-9-3, Honjo-Nishi, Kita-ku
 Osaka 531-8510
 JAPAN

Product Category(ies): **Packed Needles, PSV Sets, AVF Needles, Blood Lines,
 I.V. Catheters, Syringes with Needles,
 Blood Collection Sets**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: **JNQ235037648**

Valid from: **2019-10-31**
Valid until: **2024-05-26**

Date, **2019-10-31**

Christoph Dicks
 Head of Certification/Notified Body

TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFIKAT ◆ CERTIFICATE ◆



Benannt durch/Designated by
 Zentralstelle der Länder
 für Gesundheitsschutz
 bei Arzneimitteln und
 Medizinprodukten
 www.zlg.de
 ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System
 Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
 (Devices in Class IIa, IIb or III)

No. G1 043398 0279 Rev. 01

Facility(ies): Nipro Corporation
 3-9-3, Honjo-Nishi, Kita-ku, Osaka 531-8510, JAPAN

-/-

TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認 證 證 書 ◆ CERTIFIKAT ◆ CERTIFICADO ◆ CERTIFICAT

NIPRO (THAILAND) CORPORATION LIMITED

10/2 MOO 8 BANGNOMKO, SENA, PHRA NAKHON SI AYUTTHAYA 13110, THAILAND

TEL. +66-3520-1618 to 24 FAX: +66-3520-1625, +66-3520-1627

To whom it may concern,

Declaration of instruction for use

(MDD 93/42/EEC, Annex I)

We, Nipro (Thailand) Corporation Ltd., hereby declare that the instruction for use (IFU) are not provided for following *List of products* according to MDD Annex I Essential Requirements section 13.1.

“..., no such instructions for use are needed for devices in class I or IIa if they can be used safely without any such instructions .”

The classification for each product according to MDD is as per below

1. Syringe without Needle, Class I
2. Syringe with Needle, Class IIa
3. Hypodermic (pack) Needle , Class IIa
4. Pediatric Scalp Vein set (PSV set) , Class IIa
5. Arterial Venous Needle set (AVF Needle), AVF Single Needle, BioHole Needle , Class IIa
6. IV Catheter (Safelet Cath, Wing Cath) , Class IIa
7. Dull AVF with Scab Remover, Dull AVF Single Needle with Scab Remover, Class IIa

Authorized Signature :



Mr. Prapun Puntorn

Quality Assurance Department Manager

Nipro (Thailand) Corporation Limited

Artwork by
Mr. Thanin Prasertsri

Date
August 17th, 2017

Item Inner box	Dimension (L x W x H) 110 x 85 x 91 mm.	Colors PMS 293 C (Blue)	Reason of revision 1. Update the EC REP's information. 2. Update Nipro Corporation's address. 3. Add the language's code. 4. Add the company name and address of Malaysia representative. 5. Add the "Do not use if package is damaged" symbol. 6. Add the "Non pyrogenic" symbol.
Product Pack Needle 16G size L.	Material Duplex board 310 gsm.	Naming INCE16090WHIF	Review by
Customer Nipro CE			

100 PCS

16G

NEEDLE

NIPRO

16G

NEEDLE

NIPRO

100 PCS

16G

NEEDLE

NIPRO

INCE16090WHIF

PTA-xxxx

LOT

Uncoated Area 30 x 20 mm. (L x W)

STERILE

NIPRO CORPORATION
3-9-3, Hongji-Kishi, Kita-ku, Osaka 531-8510, JAPAN
NIPRO MEDICAL EUROPE
Bokhuisstraat 42, 2800 Mechelen, BELGIUM
(Authorized Representative in Malaysia)
NIPRO MALAYSIA SDN BHD
L13-07, Level 13, PJX-HM Shah Tower, No 16A, Persiaran Barat, 46050 Petaling Jaya, Selangor, MALAYSIA

Production Confirmation

1. Labelling area Yes No

Check by

Approved by

Comment

Customer Approval

Approved by

Artwork by
Mr. Thanin Prasertsri

Date
August 9th, 2017

Item
Inner box

Product
Pack Needle 18G size L.

Customer
Nipro CE

Dimension (L x W x H)
110 x 85 x 91 mm.

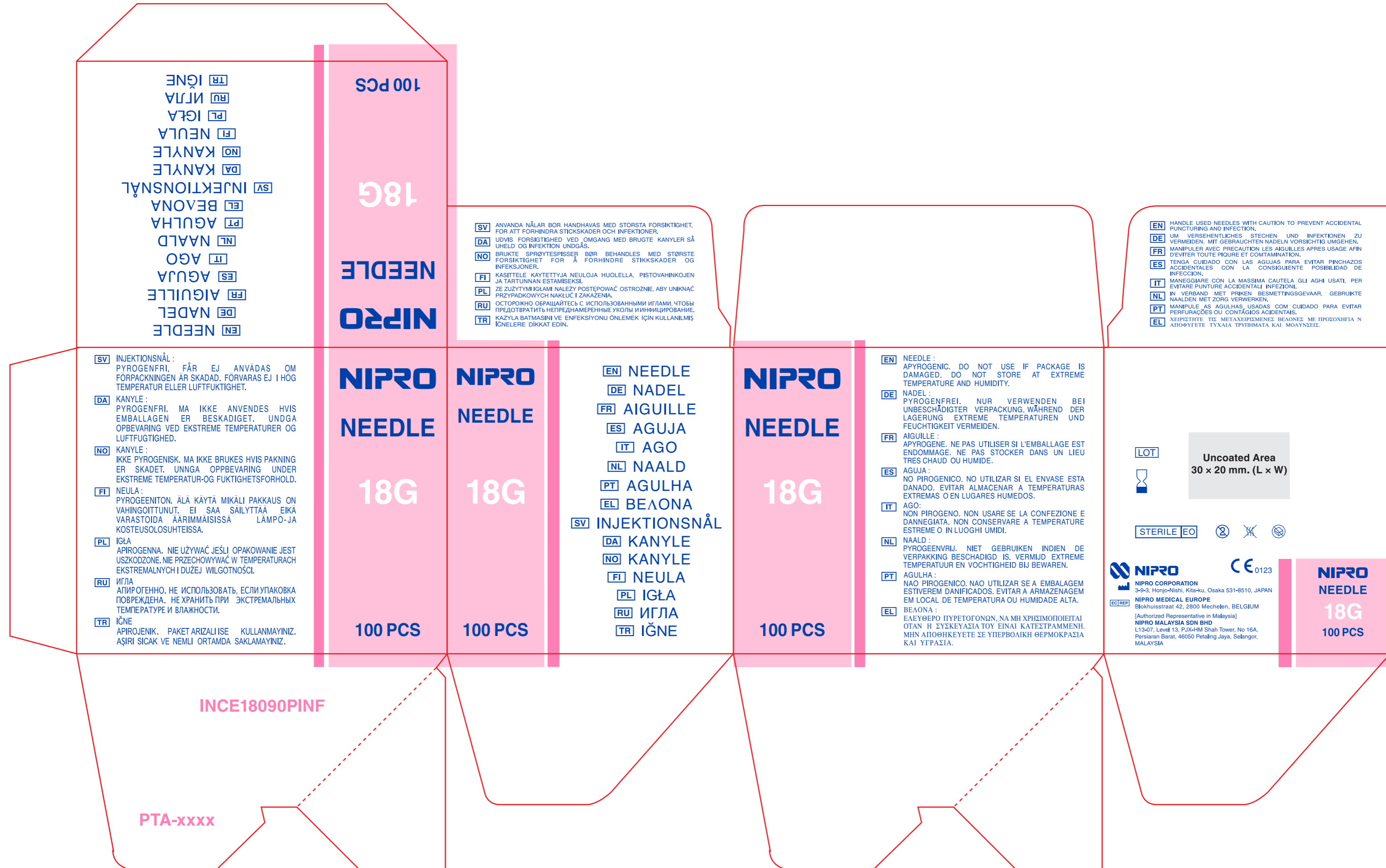
Material
Duplex board 310 gsm.

Colors
PMS 293 C (Blue)
PMS 211 C (Pink)
PMS 211 C (Pink) 50%

Naming
INCE18090PINF

Reason of revision
1. Update the EC REP's information.
2. Update Nipro Corporation's address.
3. Add the language's code.
4. Add the company name and address of Malaysia representative.
5. Add the "Do not use if package is damaged" symbol.
6. Add the "Non pyrogenic" symbol.

Review by



Production Confirmation
1. Labelling area Yes No

Check by

Approved by

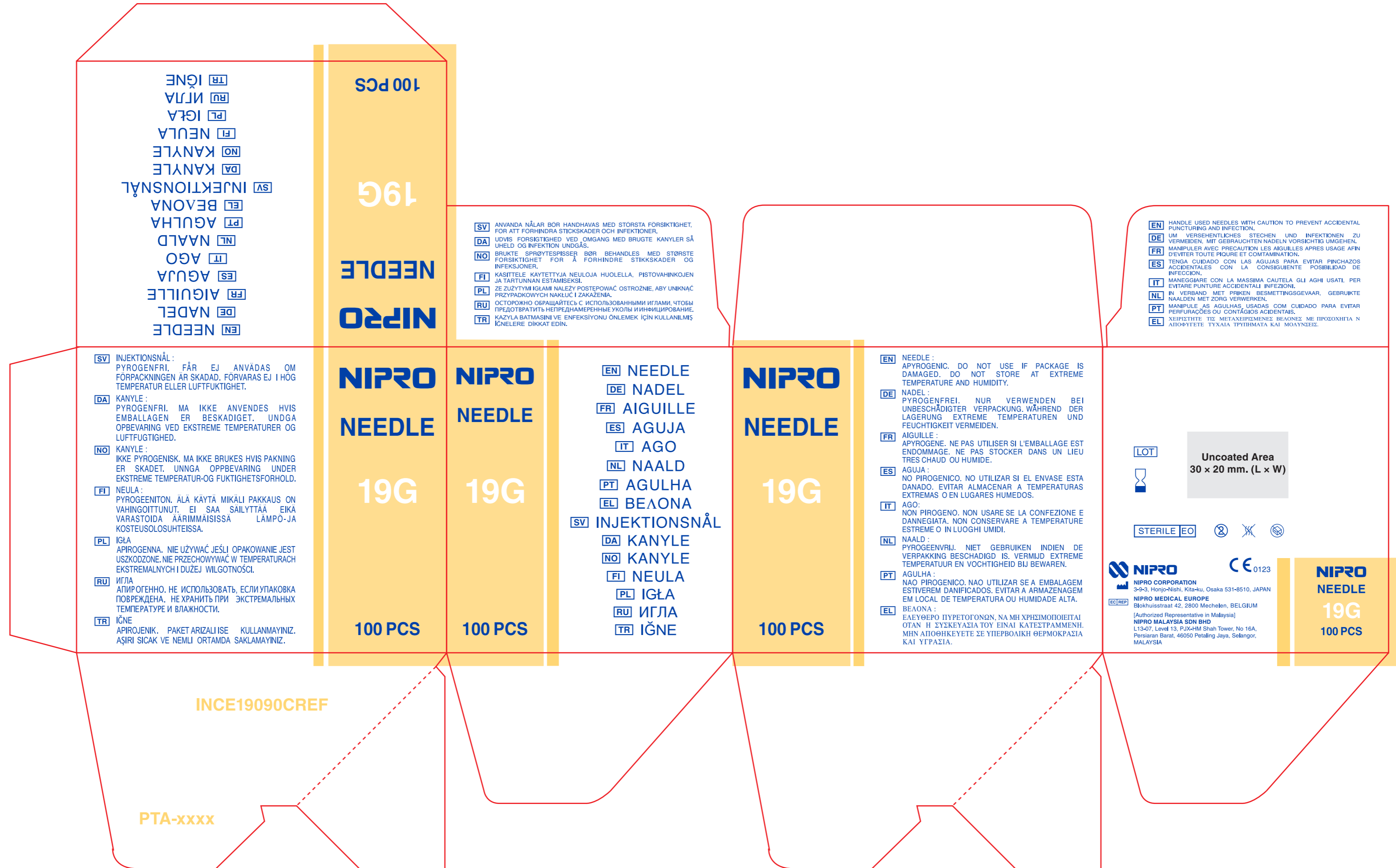
Comment

Customer Approval
Approved by

Artwork by
Mr. Thanin Prasertsri

Date
August 17th, 2017

Item Inner box	Dimension (L x W x H) 110 x 85 x 91 mm.	Colors PMS 293 C (Blue) PMS 1215 C (Cream) PMS 1215 C (Cream) 80%	Reason of revision 1. Update the EC REP's information. 2. Update Nipro Corporation's address. 3. Add the language's code. 4. Add the company name and address of Malaysia representative. 5. Add the "Do not use if package is damaged" symbol. 6. Add the "Non pyrogenic" symbol.
Product Pack Needle 19G size L.	Material Duplex board 310 gsm.	Naming INCE19090CREF	Review by
Customer Nipro CE			



Production Confirmation

1. Labelling area Yes No

Check by

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Comment

Customer Approval

Approved by

Artwork by
Mr. Thanin Prasertsri

Date
August 17th, 2017

Item
Inner box

Product
Pack Needle 20G size L.

Customer
Nipro CE

Dimension (L x W x H)
110 x 85 x 91 mm.

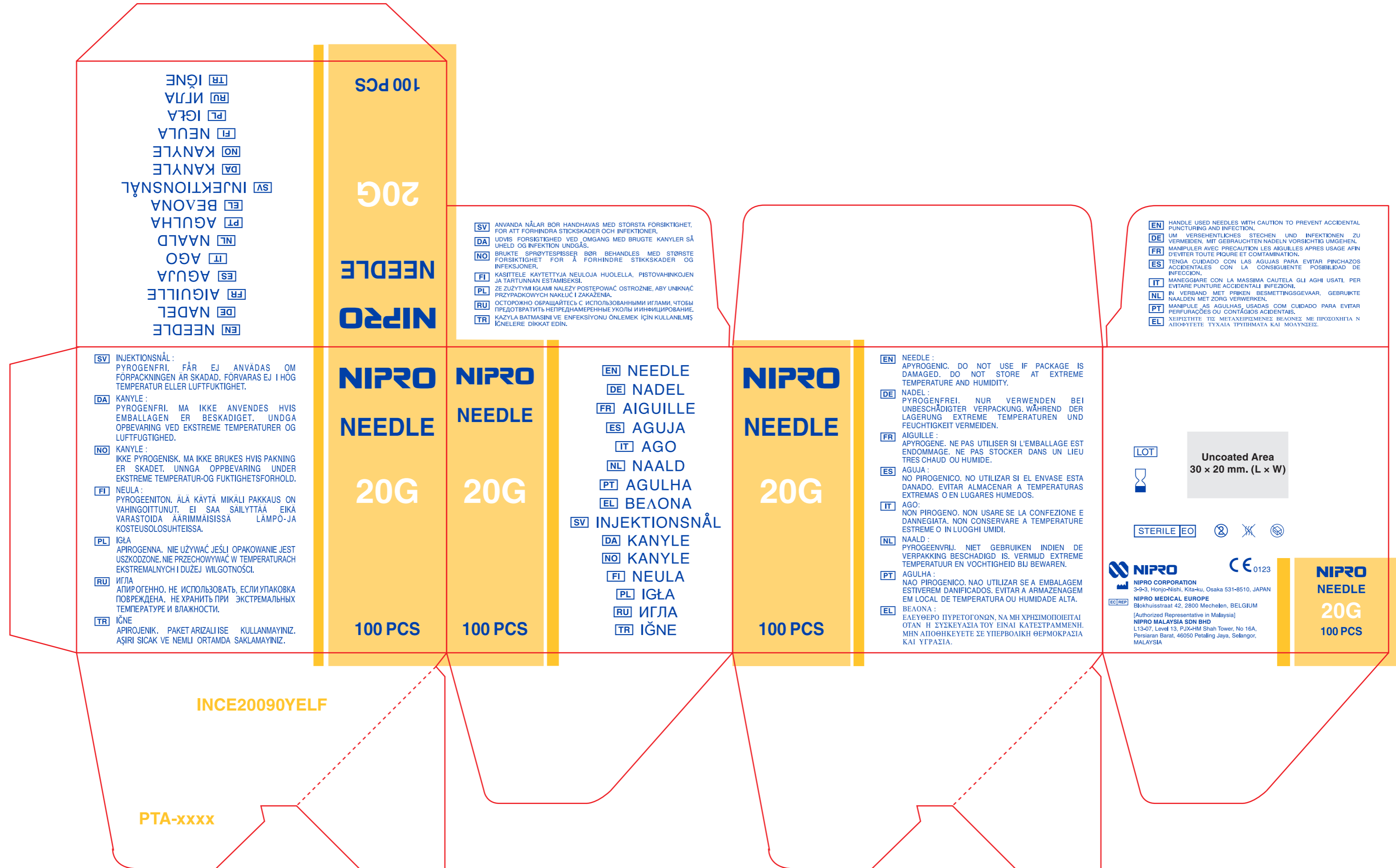
Material
Duplex board 310 gsm.

Colors
■ **PMS 293 C (Blue)**
■ **PMS 123 C (Yellow)**
■ **PMS 123 C (Yellow) 70%**

Naming
INCE20090YELF

Reason of revision
 1. Update the EC REP's information.
 2. Update Nipro Corporation's address.
 3. Add the language's code.
 4. Add the company name and address of Malaysia representative.
 5. Add the "Do not use if package is damaged" symbol.
 6. Add the "Non pyrogenic" symbol.

Review by



Production Confirmation

1. Labelling area Yes No

Check by

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Comment

Customer Approval

Approved by

Artwork by
Mr. Thanin Prasertsri

Date
August 17th, 2017

Item
Inner box

Product
Pack Needle 21G size L.

Customer
Nipro CE

Dimension (L x W x H)
110 x 85 x 91 mm.

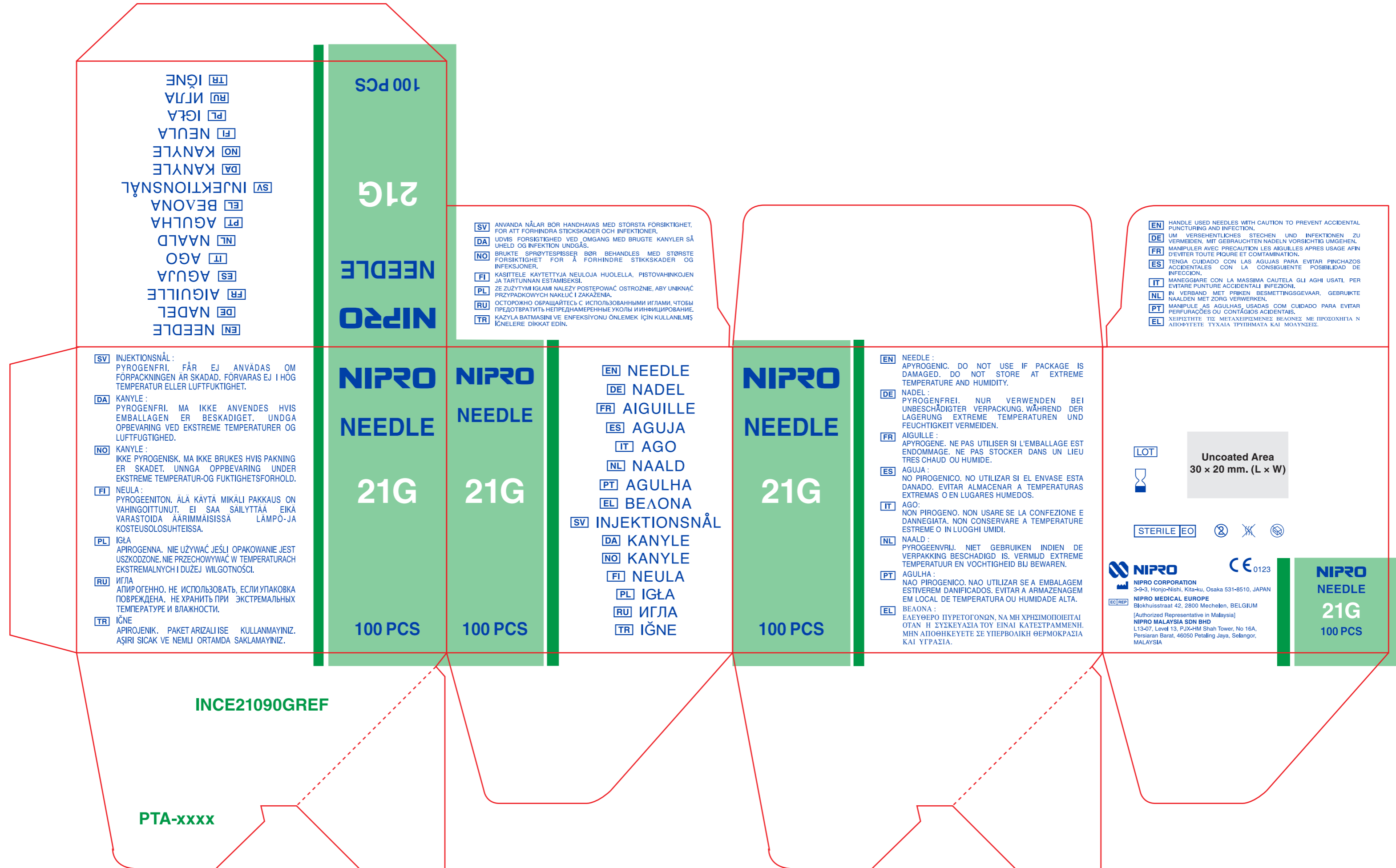
Material
Duplex board 310 gsm.

Colors
■ **PMS 293 C (Blue)**
■ **PMS 347 C (Green)**
■ **PMS 347 C (Green) 50%**

Naming
INCE21090GREF

Reason of revision
 1. Update the EC REP's information.
 2. Update Nipro Corporation's address.
 3. Add the language's code.
 4. Add the company name and address of Malaysia representative.
 5. Add the "Do not use if package is damaged" symbol.
 6. Add the "Non pyrogenic" symbol.

Review by



Production Confirmation

1. Labelling area Yes No

Check by

Approved by

Comment

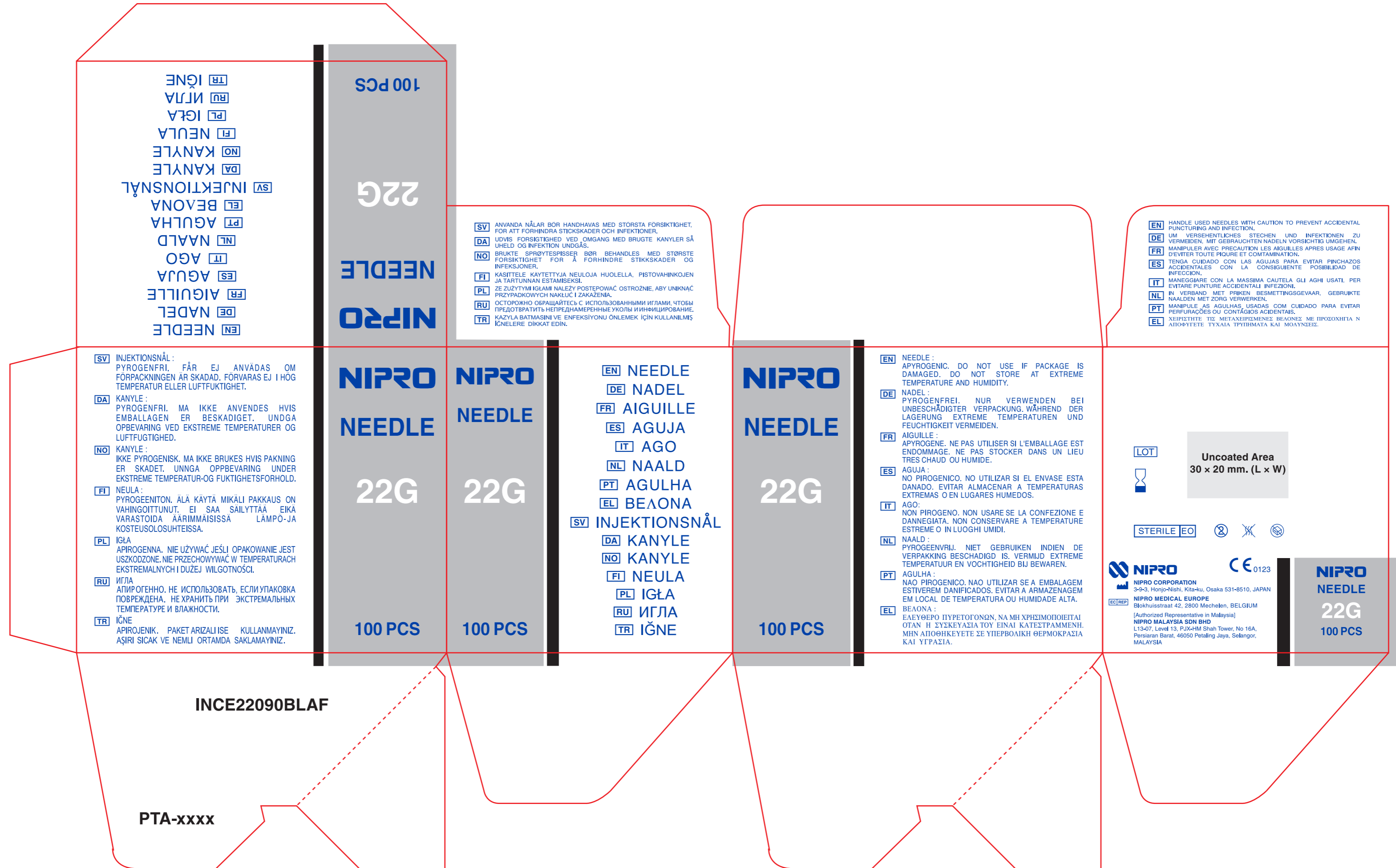
Customer Approval

Approved by

Artwork by
Mr. Thanin Prasertsri

Date
August 17th, 2017

Item Inner box	Dimension (L x W x H) 110 x 85 x 91 mm.	Colors PMS 293 C (Blue) PMS Process Black C (Black) PMS Process Black C 30%	Reason of revision 1. Update the EC REP's information. 2. Update Nipro Corporation's address. 3. Add the language's code. 4. Add the company name and address of Malaysia representative. 5. Add the "Do not use if package is damaged" symbol. 6. Add the "Non pyrogenic" symbol.
Product Pack Needle 22G size L.	Material Duplex board 310 gsm.	Naming INCE22090BLAF	Review by
Customer Nipro CE			



Production Confirmation

1. Labelling area Yes No

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Approved by

Comment

Customer Approval

Approved by

Artwork by
Mr. Thanin Prasertsri

Date
August 17th, 2017

Item
Inner box

Product
Pack Needle 23G size L.

Customer
Nipro CE

Dimension (L x W x H)
110 x 85 x 91 mm.

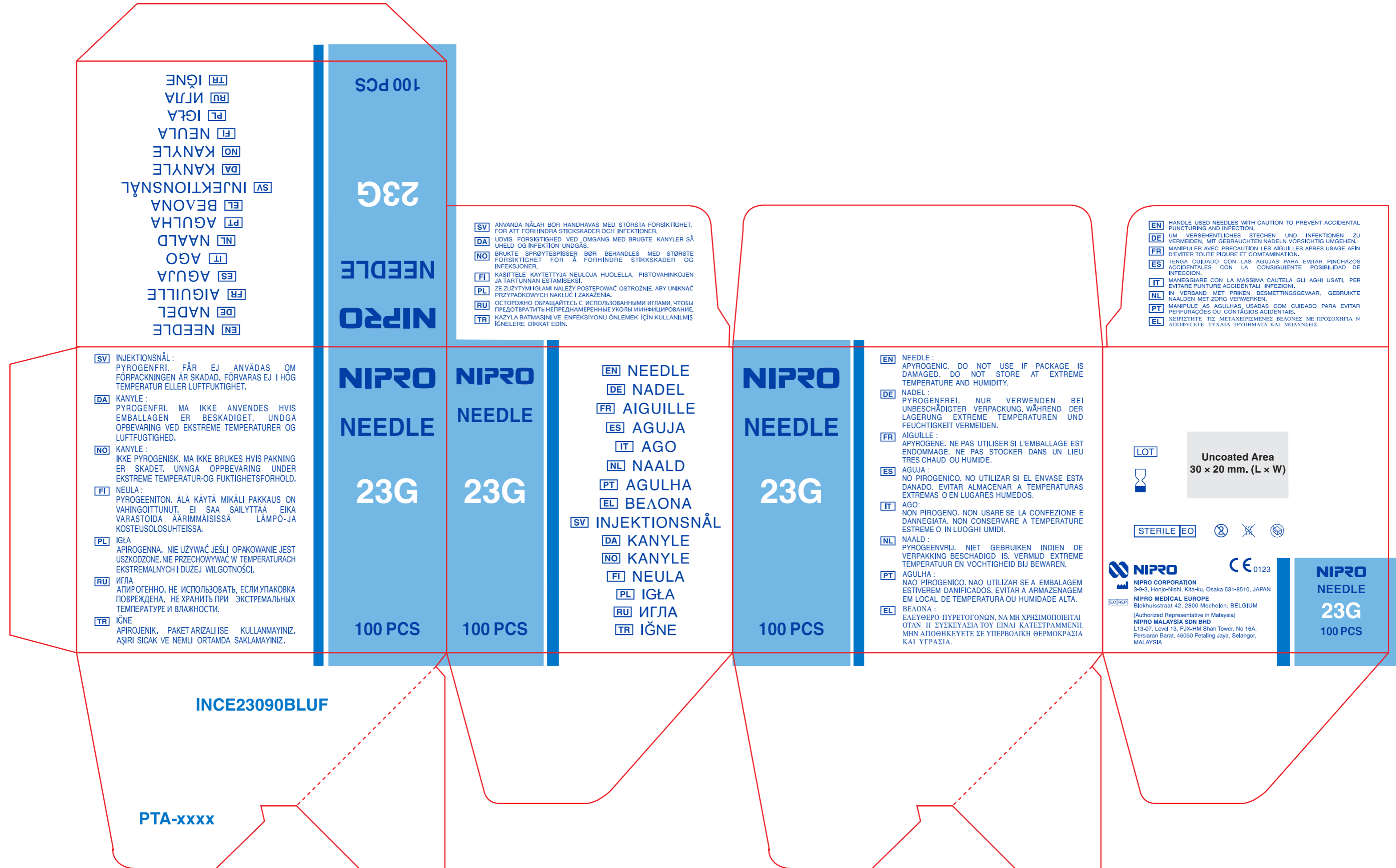
Material
Duplex board 310 gsm.

Colors
 PMS 293 C (Blue)
 PMS 3005 C (Blue)
 PMS 3005 C (Blue) 50%

Naming
INCE23090BLUF

Reason of revision
 1. Update the EC REP's information.
 2. Update Nipro Corporation's address.
 3. Add the language's code.
 4. Add the company name and address of Malaysia representative.
 5. Add the "Do not use if package is damaged" symbol.
 6. Add the "Non pyrogenic" symbol.

Review by



Production Confirmation

1. Labelling area Yes No

Check by

Approved by

Comment

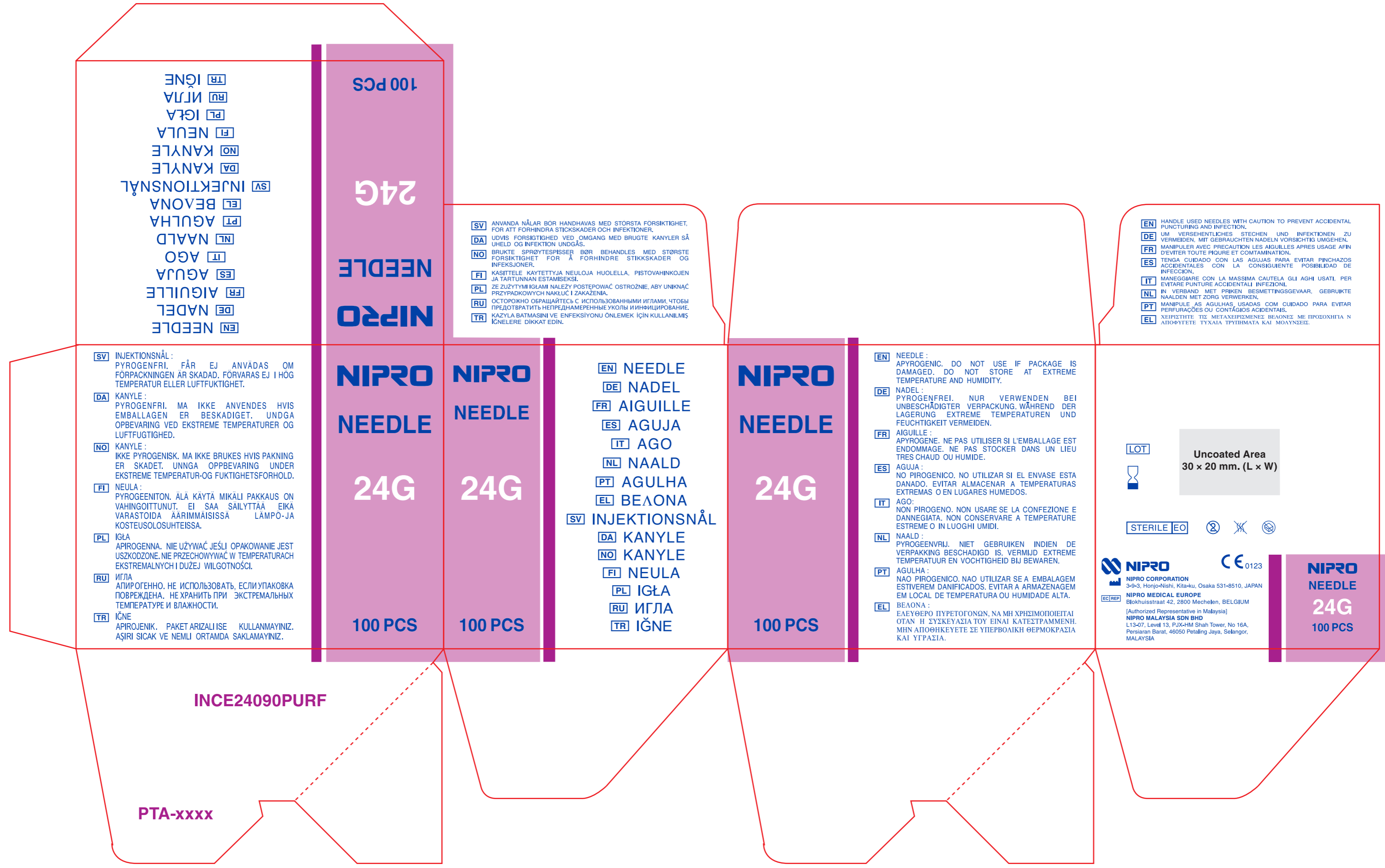
Customer Approval

Approved by

Artwork by
Mr. Thanin Prasertsri

Date
August 17th, 2017

Item Inner box	Dimension (L x W x H) 110 x 85 x 91 mm.	Colors PMS 293 C (Blue) PMS 248 C (Purple) PMS 248 C (Purple) 50%	Reason of revision 1. Update the EC REP's information. 2. Update Nipro Corporation's address. 3. Add the language's code. 4. Add the company name and address of Malaysia representative. 5. Add the "Do not use if package is damaged" symbol. 6. Add the "Non pyrogenic" symbol.
Product Pack Needle 24G size L.	Material Duplex board 310 gsm.	Naming INCE24090PURF	Review by
Customer Nipro CE			



Production Confirmation

1. Labelling area Yes No

Check by

Approved by

Comment

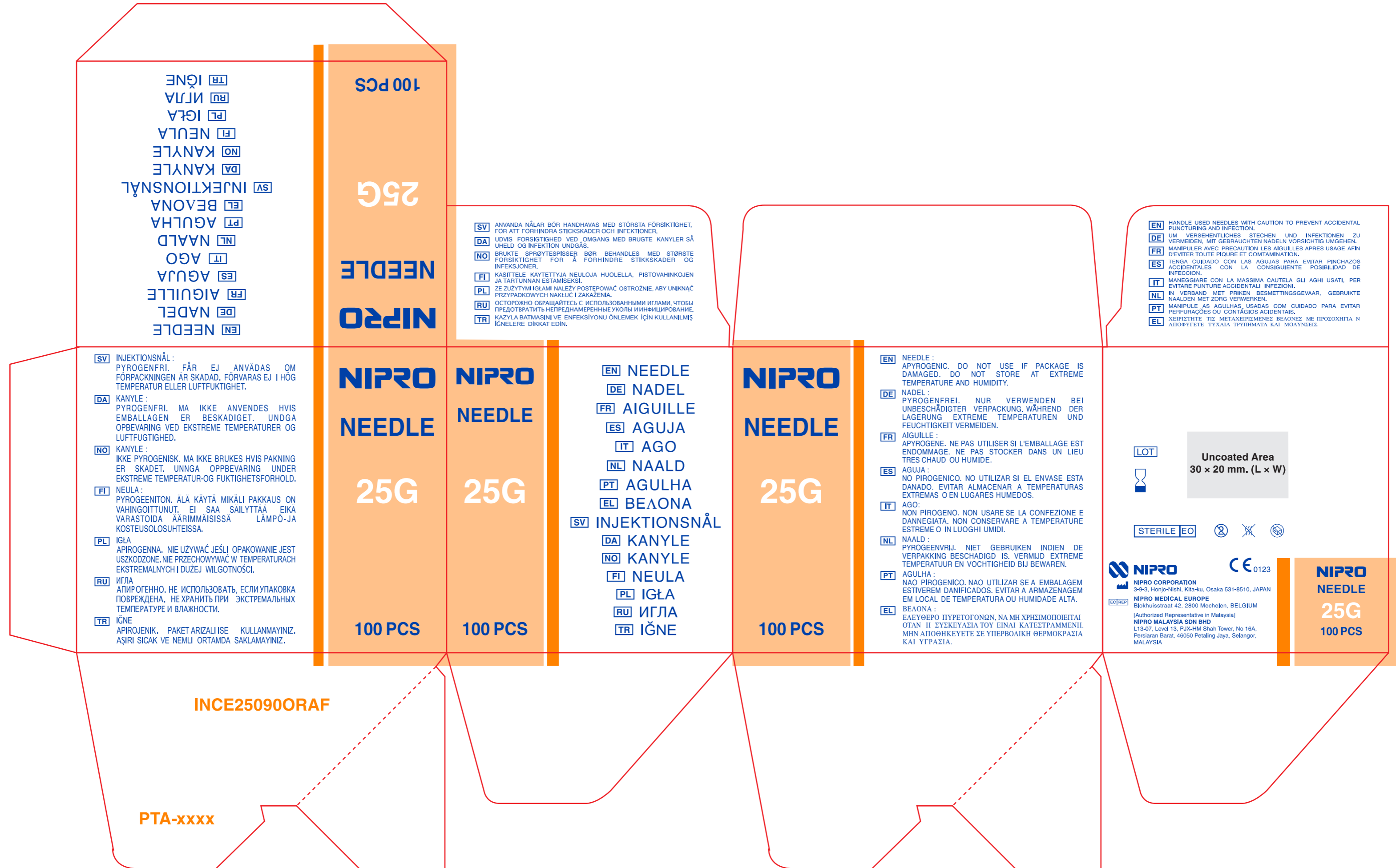
Customer Approval

Approved by

Artwork by
Mr. Thanin Prasertsri

Date
August 17th, 2017

Item Inner box	Dimension (L x W x H) 110 x 85 x 91 mm.	Colors PMS 293 C (Blue) PMS 151 C (Orange) PMS 151 C (Orange) 50%	Reason of revision 1. Update the EC REP's information. 2. Update Nipro Corporation's address. 3. Add the language's code. 4. Add the company name and address of Malaysia representative. 5. Add the "Do not use if package is damaged" symbol. 6. Add the "Non pyrogenic" symbol.
Product Pack Needle 25G size L.	Material Duplex board 310 gsm.	Naming INCE25090ORAF	Review by
Customer Nipro CE			



Production Confirmation

1. Labelling area Yes No

Check by

Approved by

Comment

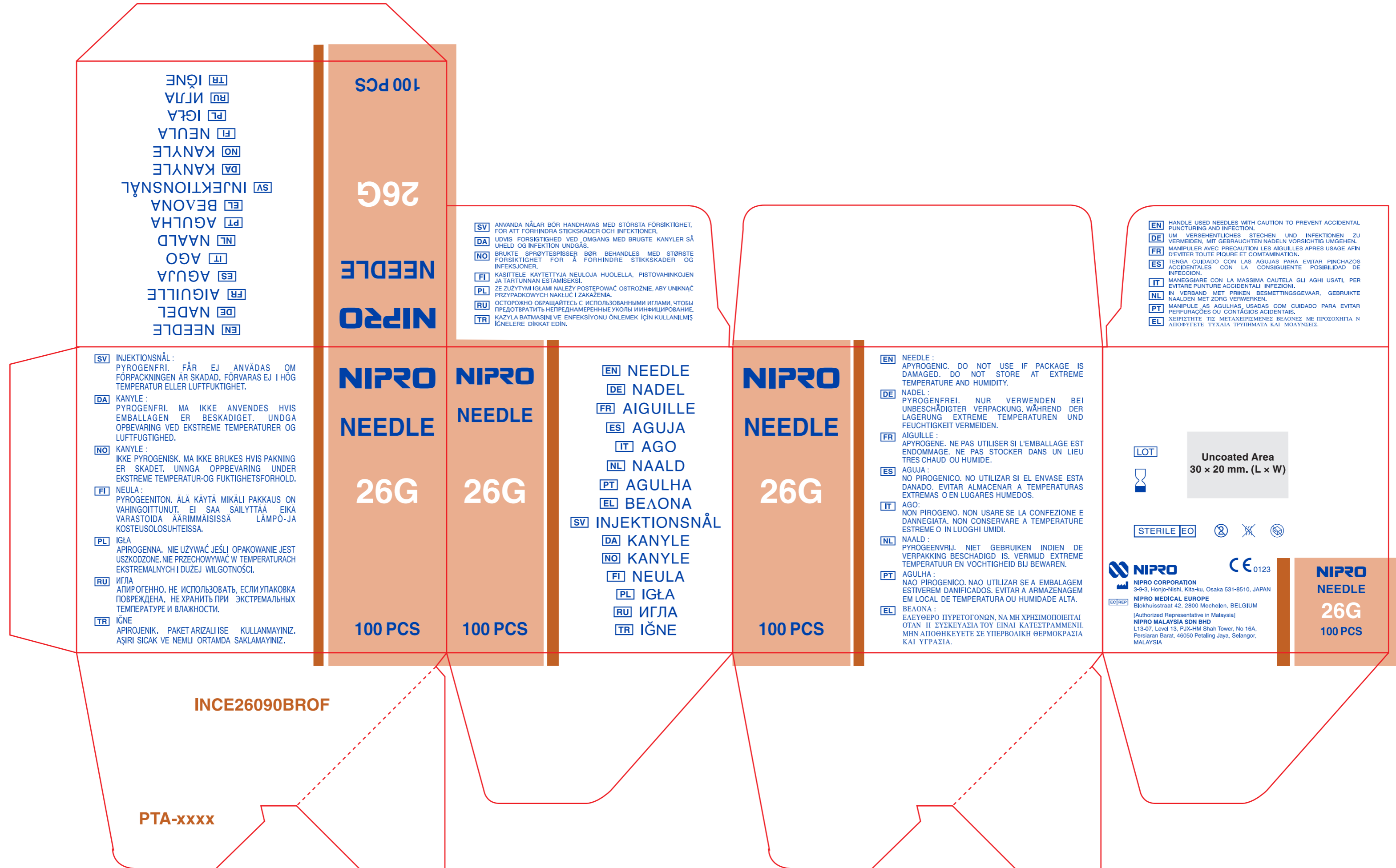
Customer Approval

Approved by

Artwork by
Mr. Thanin Prasertsri

Date
August 17th, 2017

Item Inner box	Dimension (L x W x H) 110 x 85 x 91 mm.	Colors PMS 293 C (Blue) PMS 471 C (Brown) PMS 471 C (Brown) 50%	Reason of revision 1. Update the EC REP's information. 2. Update Nipro Corporation's address. 3. Add the language's code. 4. Add the company name and address of Malaysia representative. 5. Add the "Do not use if package is damaged" symbol. 6. Add the "Non pyrogenic" symbol.
Product Pack Needle 26G size L.	Material Duplex board 310 gsm.	Naming INCE26090BROF	Review by
Customer Nipro CE			



Production Confirmation

1. Labelling area Yes No

Check by

Approved by

Comment

Customer Approval

Approved by

