ELEKTA

September 1, 2015

Tomas Herrera
U.S. Nuclear Regulatory Commission
Source Safety and Security Branch
Office of Federal and State Materials & Environmental Management Programs
Mail Stop T:8F3
Washington, DC 20555

RE: NR-0469-S-113-S

Dear Tomas;

The FDA has classified the selectSeed I-125 as an IIL product (with product code KXK). Therefore, to meet UDI (Unique Device Identifier) compliance, the labelling is required to be modified slightly. To explain the changes, please see attached the new label template specification for the *selectSeed Shipment/Sales Box label* (*150158-02).* Additionally, attached is the *Explanation of Symbols on Product Labels (777.00487 MAN)* that will be included in the selectSeed package to explain to the user the meaning of the UDI symbols.

Based on these changes, please amend the Sealed Source and Device Registry, NR-0469-S-113-S, with the updated labels as per the attached document *selectSeed labels with UDI implementation*.

The UDI implementation date for IIL products is October 24, 2015. Elekta appreciate the NRC's efforts to help achieve this goal.

Should you have any further questions or need additional information, please feel free to contact the undersigned at 770-670-2518 or via email at debra.bensen@elekta.com.

Sincerely,

Debra L. Bensen, RSO
Regulatory Affairs

Enclosures: *selectSeed Shipment/Sales Box label* (*150158-02)*
Explanation of Symbols on Product Labels (777.00487 MAN)
selectSeed labels with UDI implementation

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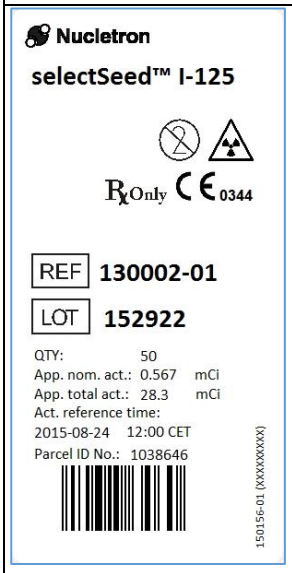
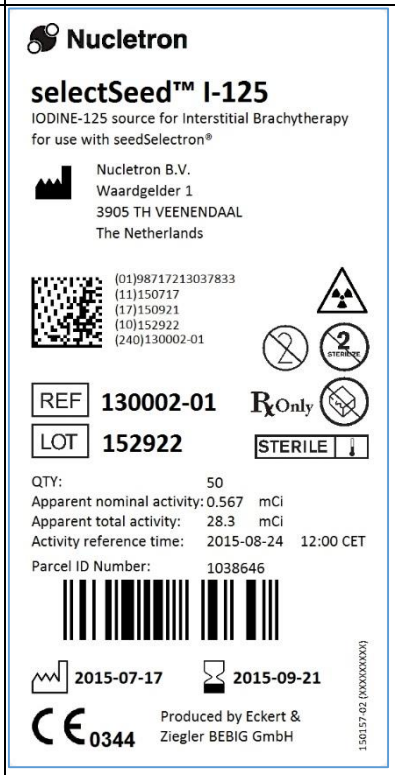
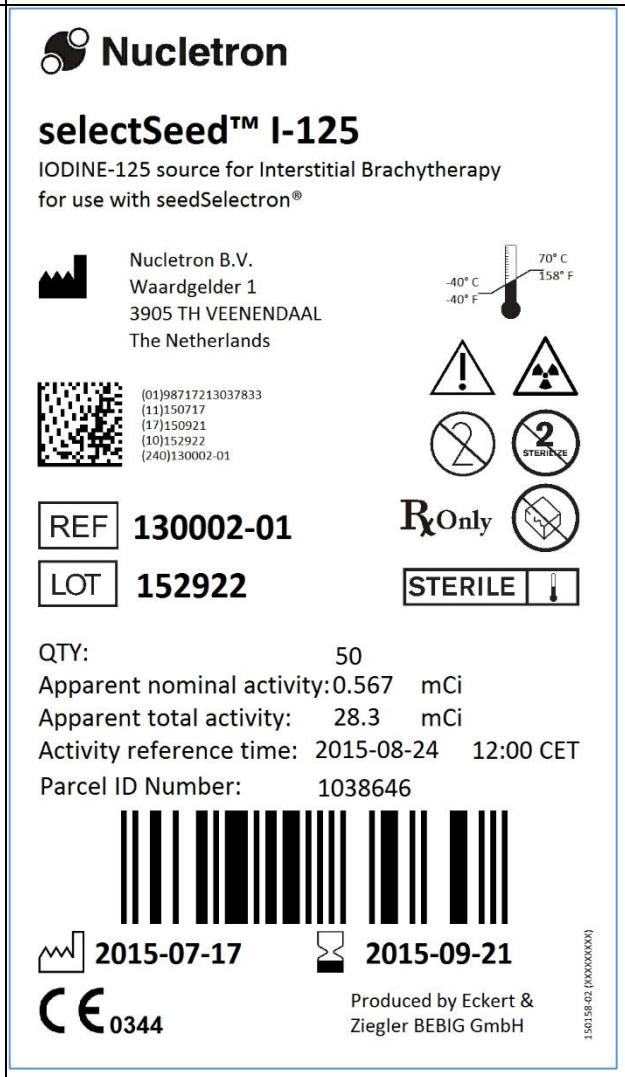
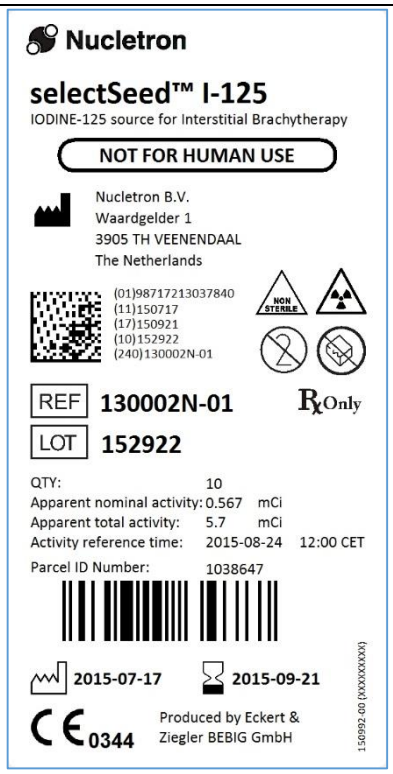
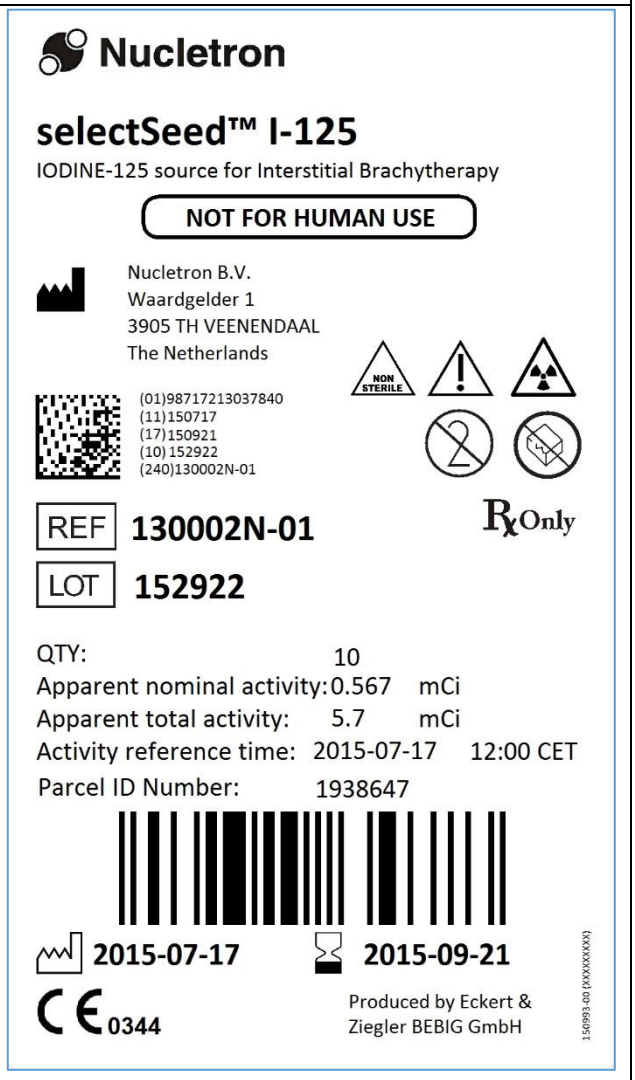
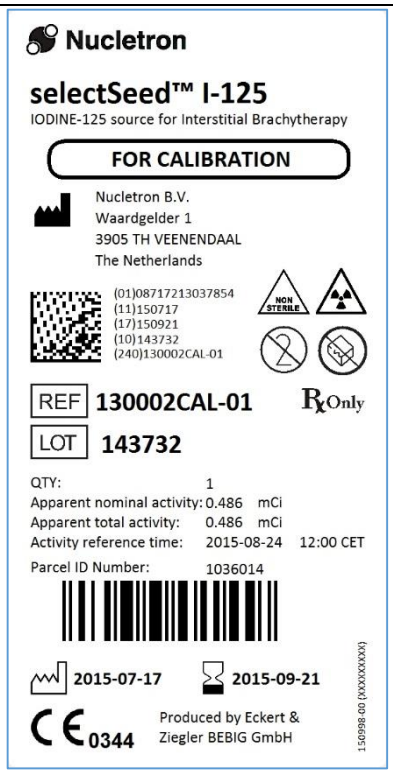
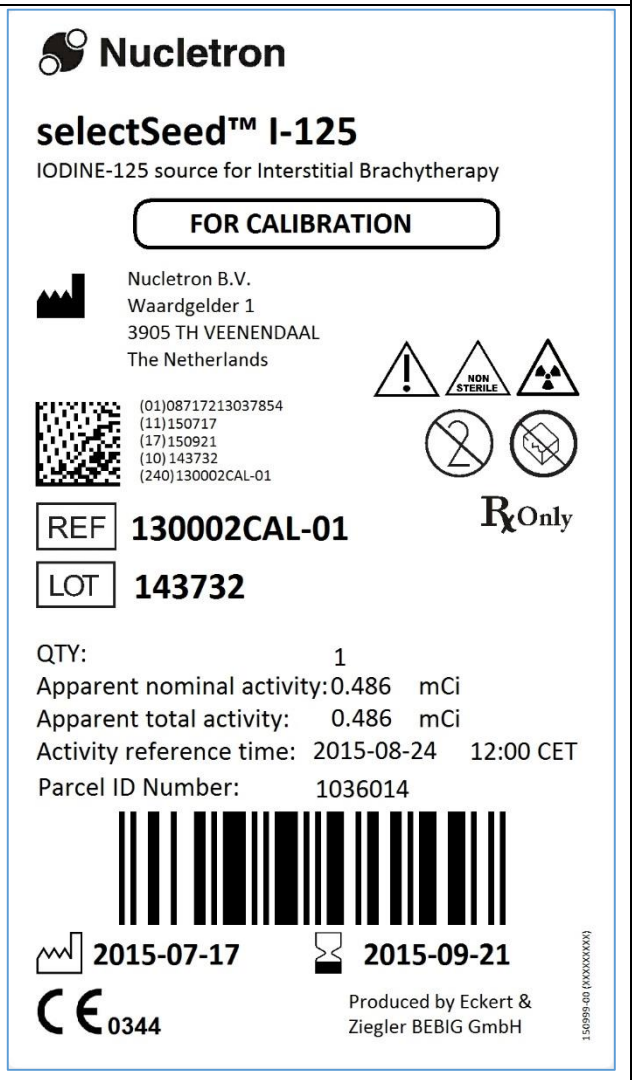
selectSeed labels with UDI implementation

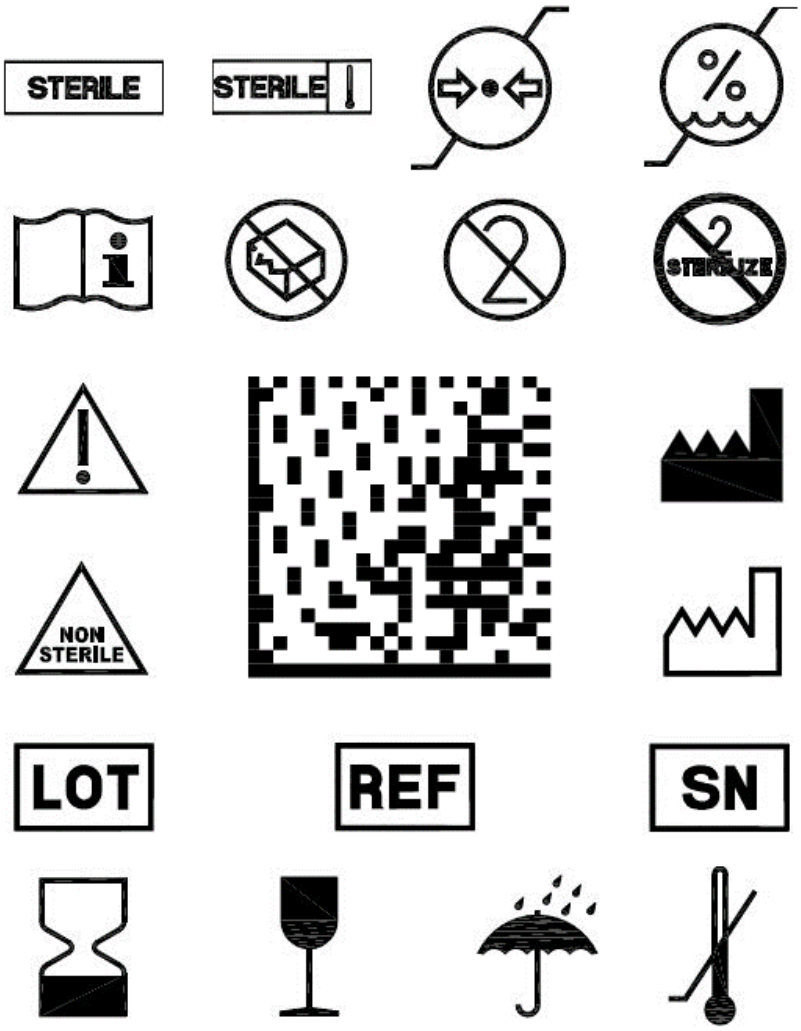
Product labeling sterile selectSeed in cartridge (130002C)		
Shielding cartridge label	Sterilization bag label	Safety product packaging label
		

Product labeling non-sterile selectSeed (130002N)		
Shielding container label	Sterilization (non-sterile) bag label	Safety product packaging label
		

Product labeling non-sterile selectSeed (130002CAL)		
Shielding container label	Sterilization (non-sterile) bag label	Safety product packaging label
		

Explanation of Symbols on Product Labels

Addendum to applicable product manuals



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Referenced documents

Elekta does not supply all the documents that we refer to in this document with the equipment. Elekta reserves the right to make the decision on which of the documents we supply with the equipment.

Contact information

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The Netherlands

CE 0344

TECHNICAL SUPPORT

Contact your local Elekta representative for technical support.
or visit www.elekta.com

English

On Elekta product labels the GS1 DataMatrix is introduced. This symbol represents the Unique Device Identification (UDI). It includes the unique product identification number (also known as Global Trade Item Number or GTIN). Depending on the product, other product data might be included. The use of the symbol and related product data is in compliance with the latest regulations (e.g. UDI rules issued by US FDA). See below an example:

(01)08717213XXXXXX
(11)YYMMDD
(17)YYMMDD
(10)XXXX
(240)XXXXXX-XX

The following GS1 Application Identifiers (AI's) might be used:
(01) - GTIN (Global Trade Item Number)
(10) – Batch or Lot number
(11) – Production date
(17) - Use by (or Expiration) date
(21) – Serial Number
(240) – Add. item identification (e.g. technical part no.)

Product Identification symbols

Manufacturer

Date of manufacture

Use by date

CE marking

LOT Batch code

REF Reference number

SN Serial number

Sterility symbols

Do not resterilize

Non sterile

Do not use if package is damaged

STERILE Sterile

STERILE A Sterile using aseptic processing techniques

STERILE EO Sterilized using ethylene oxide

STERILE R Sterilized using irradiation

STERILE Sterilized using steam or dry heat

Storage symbols

Fragile, handle with care

This way up

Keep dry

Centre of gravity

Stacking limit by number

Humidity limitation

Atmosphere pressure limitation

Lower limit of temperature

Upper limit of temperature

Temperature limitation

Safe use symbols

Radioactive material

MR Conditional

MR unsafe

Do not reuse

Caution

MR safe

Consult Instructions for Use

Disposal warning

Applied part: Type 'B' IEC 60601 series electrical safety classification

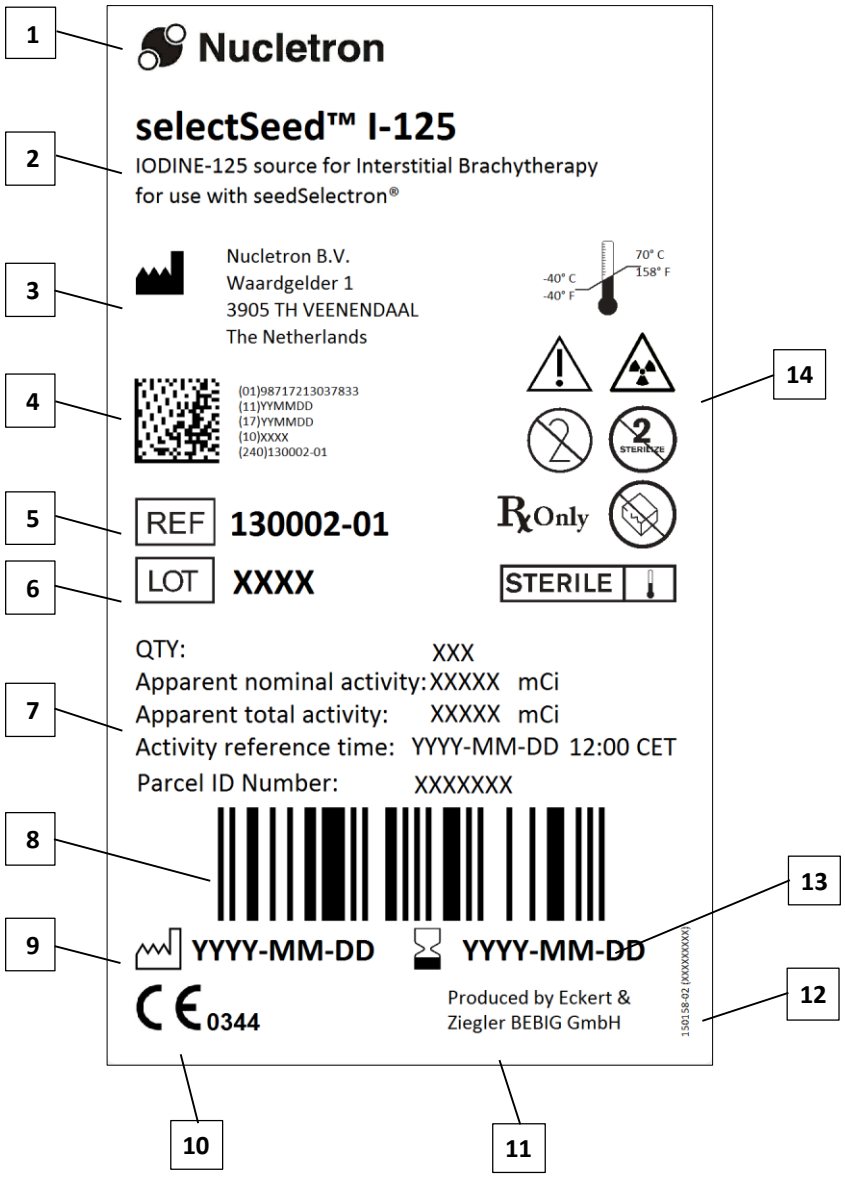
Applied part: Type 'BF' IEC 60601 series electrical safety classification

Contains or presence of natural rubber latex

Contains small amounts of DEHP. Use of this product for infants and small children is discouraged

Rx Only Symbol for prescription only. U.S. federal law restricts this device to sale by or on the order of a physician or properly licensed practitioner.

Sample of label



General Specifications	Value
Size (width x height)	80 x 140 mm
Material	050538

ID	Field	Variable	**Value** or instructions	Font or Size
1	Company Logo	N	Nucletron. Use delivered file.	30 x 12 mm
2	Product Name	N	**selectSeed™ I-125**	Calibri, pt. 16
	Product Details	N	**IODINE-125 source for Interstitial Brachytherapy for use with seedSelectron®**	Calibri, pt. 9
3	Manufacturer Name and Address	N	**Nucletron B.V., Waardgelder 1, 3905 TH Veenendaal, The Netherlands** Symbol: ISO 15223-ISO 7000-3082	Calibri, pt. 8

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4	DataMatrix	Y	Type: GS1 DataMatrix Symbol height (min): 0,255mm Symbol height (target): 0,38mm Symbol height (max): 0,495mm Quiet zone >= symbol height	
	DataMatrix content	N	AI 01 = GTIN (**98717213037833**)	Calibri, pt. 6
		Y	AI 11 = Manufacturing date in YYMMDD	Calibri, pt. 6
		Y	AI 17 = Use by date in YYMMDD (Manufacturing date plus 4 weeks = 28 days)	Calibri, pt. 6
		Y	AI 10 = Lot number	Calibri, pt. 6
		N	AI 240 = Part number including major revision	Calibri, pt. 6
5	REF	N	Reference number: **130002-01** (Technical part number including major revision) Symbol: ISO 15223-ISO 7000-2493	Calibri, pt. 14
6	LOT	Y	Lot number. Symbol: ISO 15223-ISO 7000-2492	Calibri, pt. 14
7	QTY (Quantity)	Y	Quantity specified by customer order. Format: 3 digits.	Calibri, pt. 10
	Apparent nominal activity	Y	Nominal activity per seed, in mCi, at the reference time. Format: 5 digits.	Calibri, pt. 10
	Apparent total activity	Y	Cumulative nominal activity for all seeds, in mCi, at the reference time. Format: 5 digits.	Calibri, pt. 10
	Activity reference time	Y	Date of the last Monday at 12:00 CET preceding the manufacturer date in YYYY-MM-DD	Calibri, pt. 10
	Parcel ID number	Y	Parcel ID number determined during manufacturing. Format: 7 digits	Calibri, pt. 10
8	Barcode	Y	Parcel ID and format specified by supplier.	
9	Manufacturing date	Y	Manufacturing date (date of sterilization) in format: YYYY-MM-DD. Symbol: ISO 15223-ISO 7000-2497	Calibri, pt. 12
10	CE mark	N	A minimum height of 5 mm is required to ensure that it is legible. Add also **0344**.	
11	Supplier	N	**Produced by Eckert & Ziegler BEBIG GmbH.**	Calibri, pt. 8
12	Label template number	N	Label template number of manufacturer and if necessary template number of supplier	Calibri, pt. 4
13	Used by date	Y	Manufacturing date plus 4 weeks = 28 days in YYYY-MM-DD. Symbol: ISO 15223-ISO 7000-2607	Calibri, pt. 12
14	'Radiation' symbol	N	Symbol: ISO 7010-W003	Width: 9 mm
	'Do not reuse' symbol	N	Symbol: ISO 15223-ISO 7000-1051	Diameter: 9 mm
	'Sterilized using steam or dry heat' symbol	N	Symbol: ISO 15223-ISO 7000-2503	Height: 5 mm
	'Do not resterilize' symbol	N	Symbol: ISO 15223-ISO 7000-2608	Diameter: 9 mm
	'Do not use if package is damaged' symbol	N	Symbol: ISO 15223-ISO 7000-2606	Diameter: 9 mm
	'RxOnly' symbol	N	CAUTION: US Federal Law restricts this device to prescription only.	Height: 5 mm
	'Attention, see instructions for use' symbol	N	Symbol: ISO 15223-ISO 7000-0434	Width: 9 mm
	'Temperature limitation' symbol	N	Symbol: ISO 15223-ISO 7000-0632	Height: 5 mm

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