

Miller, Debra

From: Bensen, Debbie <debbie.bensen@elekta.com>
Sent: Friday, September 16, 2016 2:31 PM
To: Sepulveda, Lymari X
Cc: Herrera, Tomas
Subject: [External_Sender] RE: Request for Additional Information
Attachments: 150905-02-02_(microSelectron 6CH 115V label template - Label template sp....pdf; 050544-00_(Distributed for US only label - Configuration Sheet).pdf; 078571-MI-01_(Brady Technical Data Sheet).pdf

Dear Lymari,

The introduction of UDI did not impact the microSelectron label dimensions, materials, location, etc. Only the text formatting on the system labels changed to create space for the UDI DataMatrix.

I attached both label specification sheets.

System label:

Dimensions: 100 x 50 mm

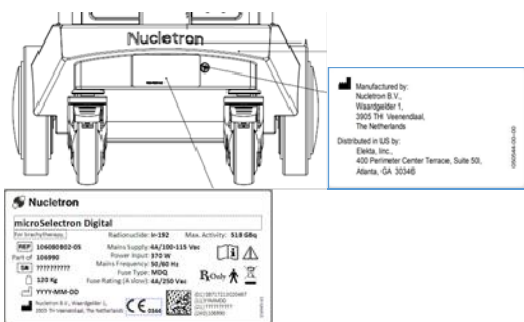
Material: Metallized Polyester (Brady B-434) [see spec sheet]

'Distributed in US by' label:

Dimensions: 50 x 25 mm

Material: Metallized Polyester (Brady B-434) [see spec sheet]

Note: The basic (raw) label material is identical, only the sizes differs.



Additionally, Elekta hereby confirms that the label attached to the treatment head when a new source is loaded has not changed.

Please let me know if you need any additional information.

Kind Regards,
Debbie

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From: Sepulveda, Lymari X [mailto:Lymari.Sepulveda@nrc.gov]
Sent: Monday, August 29, 2016 1:02 PM
To: Bensen, Debbie <debbie.bensen@elekta.com>
Cc: Herrera, Tomas <Tomas.Herrera@nrc.gov>
Subject: Request for Additional Information

Good Morning Debbie,

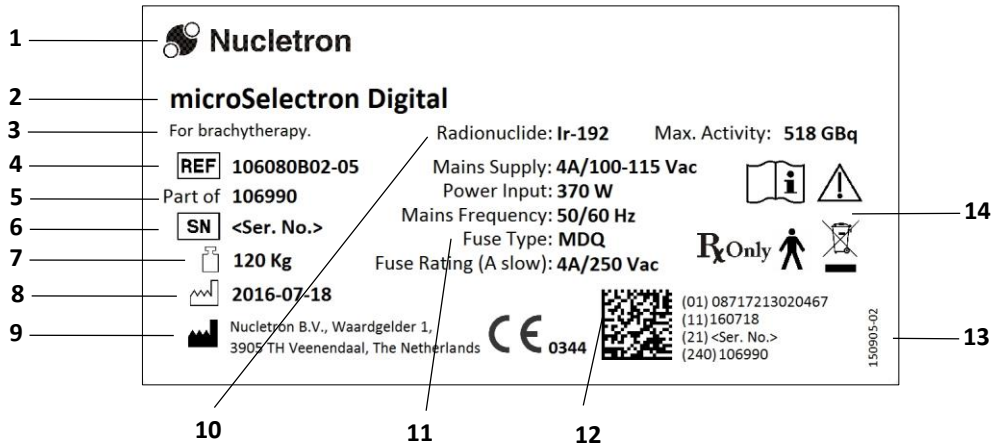
This is in response to your request to amend registration certificate NR-0469-D-114-S to include updated labels for the microSelectron device. Please provide the dimension of the labels, and indicate if the materials of construction and method of attachment has changed. In addition, please confirm that the label that is attached to the treatment head when a new source is loaded has not changed.

Please submit the requested information within 30 calendar days of the date of this e-mail. The information should be submitted in an official company letter as an attachment to an e-mail or via facsimile at 301-415-5955. If we do not receive complete information within 30 days, we will consider your request as having been abandoned by you. This is without prejudice to the submission of a complete new request.

Thank you,
Lymari Sepulveda
Mechanical Engineer
Materials Safety Licensing Branch
Division of Material Safety, State, Tribal, and Regulatory Programs
Office of Nuclear Material Safety and Safeguards

Please consider the environment before printing this e-mail.

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EXAMPLE LABEL TEMPLATE


General specifications	
Compliance with:	Labeling Architecture System and Accessories (RND-05186-00) – Column A4
Size (width x height):	100 x 50 mm

ID	Field	Variable	Value or instructions	Length	Font or size
1	Company logo	N	Nucletron. Use Nucletron-ZW-small.png.		25 x 5 mm
2	Product Name	N	Fixed text: microSelectron Digital		
3	Additional description	N	Fixed text: For brachytherapy.		Calibri, 7 pt.
4	REF	N	Reference number (technical part number including major revision). Fixed text: 106080B02-05 . Symbol: ISO 7000-2493.		Calibri, 8 pt.
5	Part of 106990	N	Reference to the commercial part number		Calibri, 8 pt.
6	SN	Y	Serial number with a Prefix followed by a 3-digit number between 001 and 999. Prefix and number will be filled in during printing of the label. Symbol: ISO 7000-2498.	10	Calibri, 8 pt.
7	Mass	N	Mass of the device in kg. Fixed text: 120 Kg . Symbol: ISO 7000-1321A.		Calibri, 8 pt.
8	Manufacturing date	Y	Format YYYY-MM-DD. Symbol: ISO 7000-2497.	10	Calibri, 8 pt.
9	Manufacturer name and address	N	Fixed text: Nucletron B.V., Waardgelder 1, 3905 TH Veenendaal, The Netherlands. Symbol: ISO 7000-3082.		Calibri, 6 pt.
10	Radionuclide	N	Fixed text: Ir-192		Calibri, 8 pt.
	Max. Activity	N	Fixed text: 518 GBq		Calibri, 8 pt.
11	Mains Supply	N	Fixed text: 4A/100-115 Vac		Calibri, 8 pt.
	Power Input	N	Fixed text: 370 W		Calibri, 8 pt.
	Mains Frequency	N	Fixed text: 50/60 Hz		Calibri, 8 pt.
	Fuse Type	N	Fixed text: MDQ		Calibri, 8 pt.
	Fuse Rating (A slow)	N	Fixed text: 4A/250 Vac		Calibri, 8 pt.
12	DataMatrix		DataMatrix according to GS1 specification for GS1 data matrix ECC200: <ul style="list-style-type: none"> • X-dimension: Min. = 0.255 mm; Target = 0.380 mm; Max = 0.495 mm. • Height is determined by X-dimension and data that is encoded. • Quiet Zone: 1x X-dimension on all four sides. • Minimum quality: 1.5/08/660. 		

	Bar code content	N	AI 01 = GTIN - Fixed value: 08717213020467		Calibri, 6 pt.
		Y	AI 11 = Manufacturing date in YYMMDD	6	Calibri, 6 pt.
		Y	AI 21 = Serial number	10	Calibri, 6 pt.
		N	AI 240 = Commercial part number - Fixed value: 106990		Calibri, 6 pt.
13	Label template no.	N	Elekta label template number.		Calibri, 5 pt.
14	Consult instructions for use	N	Symbol: ISO 7000-1641		Height: 6 mm
	Attention, see instructions for use	N	Symbol: ISO 7000-0434		Height: 6 mm
	CE mark	N	A minimum height of 5 mm is required. Add also 0344.		Height: 6 mm
	RxOnly	N	US federal law restricts this device to prescription only.		Height: 6 mm
	WEEE marking	N			Height: 7 mm
	Applied part symbol	N	Symbol: IEC 60601-1: 2005 7.2.10		Height: 6 mm



NB00475[00]

Sample of label:



Specification	Value
Size	50 x 25 mm
Material	050280
Label Format	LBL (use NiceLabel Pro for printing)
Placement instructions	136872

BRADY B-434 THERMAL TRANSFER PRINTABLE GLOSS METALLIZED POLYESTER LABEL STOCK

TDS No. B-434
 Effective Date: 12-Jul-2010

Description:

GENERAL

Print Technology: Thermal Transfer
Material Type: Metallized Polyester
Finish: Glossy
Adhesive: Permanent Acrylic

APPLICATIONS

Rating plate and general purpose labeling on textured surfaces.

RECOMMENDED RIBBONS

Brady Series R4900
 Brady Series R6000
 Brady Series R6000HF

REGULATORY/AGENCY APPROVALS

UL: B-434 is a UL Recognized Component when printed with the Brady R4900 and R6000 Series ribbons. See UL file MH17154 for specific details. UL information can be accessed online at UL.com. Search in *Certifications* area.

CSA: B-434 is a CSA Accepted material when printed with the Brady R4900 and R6000 Series ribbon. See CSA Acceptance Record LS 41833 for specific details. CSA information can be accessed online at directories.csa-international.org.

Brady B-434 is RoHS compliant to 2005/618/EC MCV amendment to RoHS Directive 2002/95/EC.

SPECIAL FEATURES

B-434 is designed to withstand numerous solvents while maintaining excellent image quality.

Details:

PHYSICAL PROPERTIES	TEST METHODS	AVERAGE RESULTS
Thickness	ASTM D 1000 -Substrate -Adhesive -Total	0.002 inch (0.051 mm) 0.002 inch (0.051 mm) 0.004 inch (0.102 mm)
Adhesion to: -Stainless Steel	ASTM D 1000 20 minute dwell 24 hour dwell	86 oz/in (94 N/100 mm) 97oz/in (106 N/100 mm)
-Textured ABS	20 minute dwell 24 hour dwell	14 oz/in (15 N/100 mm) 18 oz/in (20 N/100 mm)
-Polypropylene	20 minute dwell 24 hour dwell	67 oz/in (73 N/100 mm) 77 oz/in (84 N/100 mm)
Tack	ASTM D 2979 Polyken™ Probe Tack 1 second dwell	47 oz (1333 g)

Tensile Strength and Elongation	ASTM D 1000 -Machine Direction	42 lbs/in (736 N/100 mm), 118%
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The following testing was performed on B-434 samples printed with Brady Series R4900, R6000 and R6000HF ribbons. Samples laminated to aluminum panels. All samples allowed to dwell 24 hours prior to testing. Unless noted, results are the same for all three ribbons.

PERFORMANCE PROPERTIES	TEST METHODS	EFFECT TO TAPE	EFFECT TO PRINT
Long Term High Service Temperature	30 days at 194 °F (90 °C)	No visible effect	No visible effect
Long Term Low Service Temperature	30 days at -40 °F (-40 °C)	No visible effect	No visible effect
Humidity Resistance	30 days at 100 °F (37 °C), 95% R.H.	No visible effect	No visible effect
UV Light Resistance	30 days in UV Sunlighter™ 100	Slight yellowing of label	No visible effect
Weatherability	ASTM G155, Cycle 1 30 days in Xenon Arc Weatherometer	Topcoat becomes chalky	No visible effect
Abrasion Resistance	Taber Abraser, CS-10 grinding wheels, 500 g/arm (Fed. Std. 191A, Method 5306)	No visible effect	Print legible up to: R4800 50 cycles R4900 40 cycles R6000 135 cycles

PERFORMANCE PROPERTY	SOLVENT RESISTANCE
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Samples printed with Series R4900, R6000 and R6000HF ribbons. Labels printed using a 3:1 barcode ratio with a 5 mil narrow X dimension bar. Test was conducted at room temperature after 24 hour dwell. Testing consisted of 5 cycles of 10 minute immersions in the specified chemical reagent followed by 30 minute recovery period. Samples rubbed 10 times with a cotton swab immersed in test fluid after final immersion.

CHEMICAL REAGENT	SUBJECTIVE OBSERVATION OF VISUAL CHANGE				
	LABEL STOCK	PRINTING IMMERSION ONLY ¹	R4900 PRINT WITH COTTON SWAB RUB	R6000 PRINT WITH COTTON SWAB RUB	R6000HF PRINT WITH COTTON SWAB RUB
Methyl Ethyl Ketone	Slight adhesive ooze	Print Removed	Print Removed	Print Removed	Print Removed
1,1,1-Trichloroethane	Slight adhesive ooze	NVE ²	Print Removed	Slight Removal	Obsolete
Toluene	Slight adhesive ooze	NVE	Print Removed	Print Removed	Print Removed
Isopropyl Alcohol	NVE	NVE	NVE	NVE	NVE
Mineral Spirits	NVE	NVE	NVE	NVE	NVE
JP-4 Jet Fuel	NVE	NVE	NVE	NVE	NVE
ASTM Reference Fuel B	NVE	NVE	NVE	NVE	Not Tested
SAE 20 WT Oil	NVE	NVE	NVE	NVE	NVE
ASTM #3 Oil	NVE	NVE	NVE	NVE	NVE
Mil 5606 Oil	NVE	NVE	NVE	NVE	NVE
Skydrol® 500B-4	Slight adhesive ooze	Print Removed	Print Removed	Print Removed	Print Removed
Super Agitene®	NVE	NVE	NVE	NVE	NVE
BIOACT® EC-7R™	NVE	NVE	NVE	NVE	NVE
Deionized	NVE	NVE	NVE	NVE	NVE

Water					
3% Alconox® Detergent	NVE	NVE	NVE	NVE	NVE
10% Sodium Hydroxide Solution	NVE	NVE	NVE	NVE	NVE
10% Sulfuric Acid Solution	NVE	NVE	NVE	NVE	NVE

¹Results same for R4900, R6000 and R6000HF ribbons

²NVE=No Visible Effect

Product testing, customer feedback, and history of similar products, support a customer performance expectation of at least **two years from the date of receipt** for this product as long as this product is stored in its original packaging in an environment *below 80 degrees F (27 °C) and 60% RH*. We are confident that our product will perform well beyond this time frame. However, it remains the responsibility of the user to assess the risk of using such product. We encourage customers to develop functional testing protocols that will qualify a product's fitness for use, in their actual applications.

Trademarks:

Alconox® is a registered trademark of Alconox Co.
 BIOACT® is a registered trademark of Petroferm, Inc.
 BradyPrinter™ is a trademark of Brady Worldwide, Inc.
 EC-7R™ is a trademark of Petroferm Inc.
 Polyken™ is a trademark of Testing Machines Inc.
 Skydrol® is a registered trademark of the Monsanto Company
 Sunlighter™ is a trademark of the Test Lab Apparatus Company
 Super Agitene® is a registered trademark of Graymills Corporation
 ASTM: American Society for Testing and Materials (U.S.A.)
 CSA: Canadian Standards Association
 SAE: Society of Automotive Engineers (U.S.A.)
 UL: Underwriters Laboratories Inc. (U.S.A.)
 All S.I. Units (metric) are mathematically derived from the U.S. Conventional Units.

Note: All values shown are averages and should not be used for specification purposes. Test data and test results contained in this document are for general information only and shall not be relied upon by Brady customers for designs and specifications, or be relied on as meeting specified performance criteria. Customers desiring to develop specifications or performance criteria for specific product applications should contact Brady for further information.

Product compliance information is based upon information provided by suppliers of the raw materials used by Brady to manufacture this product or based on results of testing using recognized analytical methods performed by a third party, independent laboratory. As such, Brady makes no independent representations or warranties, express or implied, and assumes no liability in connection with the use of this information.

WARRANTY

Brady products are sold with the understanding that the buyers will test them in actual use and determine for themselves their adaptability to their intended uses. Brady warrants to the buyers that its products are free from defects in material and workmanship, but limits its obligation under this warranty to replacement of the product shown to Brady's satisfaction to have been defective at the time Brady sold it. This warranty does not extend to any persons obtaining the product from the buyers. This warranty is in lieu of any other warranty, express or implied, including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose, and of any other obligations or liability on Brady's part. Under no circumstances will Brady be liable for any loss, damage, expense, or consequential damages of any kind arising in connection with the use, or inability to use, Brady's products.

Specification Of Thermal Transfer Printable Labels

Application(s): General & Industrial Identification

Agency: CSA Approved, UL Recognized

Approval(s)/Compliance:

Size: 3.000" W x 2.000" H (76.200 mm W x 50.800 mm H)

Printable Area: 3.000" W x 2.000" H (76.200 mm W x 50.800 mm H)

Web Width: 3.200" (81.28 mm)

Label Type/Style: Label

Vertical Repeat: 2.125" (53.98 mm)

Color: Silver

Finish: Gloss

Qty Per Row: 1

Material Type: Polyester

Material Description: Metallized Polyester

Brady Material #: [B-434](#)

General ID Catalog: [pg. 34](#)

Recommended Ribbon Series: 6000

Suggested Ribbon Part#: R6002

Acceptable Ribbon Series: 6200, 4900, 4800

Printer Compatibility: BBP81, Brady 1244, Brady 1344, Brady 200MVP Plus, Brady 2461, Brady 300MVP Plus, Brady 300X-Plus II, Brady 3481, Brady 360X-Plus II, Brady 600X-Plus II, Brady 6441, Brady IP, Tagus T200, Tagus T300, Thermal Transfer Printers

Surface: Smooth, Textured/Rough

RoHS Compatibility: Compliant with RoHS Directive. NOTE: All statements concerning RoHS Directive compliance refer to 2005/618/EC MCV amendment to RoHS Directive 2002/95/EC. Product compliance is based upon information provided by suppliers of the raw materials used by Brady to manufacture these products, or by independent laboratory testing of these products. As such, Brady makes no independent representations or warranties, express or implied, and assumes no liability in connection with the use of this information.

QTY/UOM: 1,000/Roll