



The Global Language of Business

Sample UDI Labels

UDI Label Examples, HRI & Date Formatting...

GS1 Healthcare



UDI Example - #1... Medtronic... ...1D/Linear GS1-128



US FDA UDI required
ISO 8601 date format

Device Identifier (DI)
"Static" portion
GTIN (product identifier)

Production Identifier (PI)
"Dynamic" portion
Application Identifiers (e.g. serial, lot number & expiry date)



UDI Example - #2... B.Braun... ...2D/Matrix GS1 DataMatrix



H.E.L.P. Acetate Buffer pH 4.85

4 x 3000 ml

CA/GB Sodium acetate buffer solution for use ONLY with extracorporeal H.E.L.P. apheresis

Caution: Federal Law (U.S.) restricts this device to sale by or on order of a physician.

CA/FR: Solution tampon d'acetate de sodium destinée à une utilisation UNIQUEMENT avec aphérèse H.E.L.P. extracorporelle

sterile / stérile

Endotoxin-FREE and non-pyrogenic/ Ne contient pas d'endotoxines et non-pyrogène

SINGLE USE only, discard unused portion/ À USAGE UNIQUE seulement, jeter la portion inutilisée
DO NOT add any additives/ NE PAS ajouter d'additifs

NOT for intravenous infusion/ NON adapté à une perfusion intraveineuse

ONLY USE if solution is clear and colourless/ UTILISER UNIQUEMENT si la solution est limpide et incolore
ONLY USE if container and connections are not damaged/ Ne pas utiliser si l'emballage et les connections sont endommagées

Keep out of the reach of children/ Conserver la solution hors de portée des enfants

Sodium acetate x 3 H₂O 27.22 g/l
Acetic acid 99% 6.82 g/l

DIN: 02373807



074113/B

Manufacturer:

B | BRAUN

B. Braun Avitum AG
34209 Melsungen
Germany



Article no.: 4113



Batch no.: 0350214



Manuf. date: 2014-03-04



Expiry date: 2017-02-28

Canadian Distributor:

Chief Medical Supplies Ltd.
411-19th Street S.E.
Calgary, Alberta T2E 6J7

Production site:

B. Braun Avitum AG
Kattenvenner Str., 32
49219 Glandorf, Germany
Made in Germany

US Distributor:

B. Braun Medical Inc.
Bethlehem, PA 18018-3524

(01)04046964290169

(7)170228(11)140304(10)0350214

Device Identifier (DI)

“Static” portion

GTIN (product identifier)

Production Identifier (PI)

“Dynamic” portion

Application Identifiers (e.g. serial, lot number & expiry date)

US FDA UDI required

ISO 8601 date format



UDI & the GS1 system... date formats...



Example Label

GS1 Healthcare Products
FMD (Fictitious Medical Device)

Manufacturer:
GS1 Global Office
Avenue Louise 326
BE 1050 Brussels
+32 2 788 7800

2014-11-20

LOT 7654321D

(01) 09504000059118
(17) 141120
(10) 7654321D
(21) 10987654d321

Non-HRI Text

Characters (i.e. letters, numbers, graphic symbols) which can be interpreted by people and may or may not be encoded in GS1 AIDC data carriers (i.e. not confined to a structure & format based on GS1's standards).

Controlled by Regulators & Manufacturers!

Date Format in "Non-HRI Text"

ISO 8601 based UDI date format required by the US FDA for "Non-HRI" illustration of Medical Device dates (e.g. Expiry, Manufacturing, etc.)

Note: Though optional for ISO, the "dashes" (-) are required by the US FDA.

US FDA format mandate!

HRI (Human Readable Interpretation)

Characters (i.e. letters and numbers) which can be read by people and are encoded in GS1 AIDC data carriers, confined to GS1's standard structure and format. HRI is a one-to-one illustration of the encoded data. Note that Start, Stop, Shift & Function characters, and any Symbol Check Characters, are not shown in the HRI.

The US FDA requires labelers to follow the rules of their UDI Issuing Agency... this is part of GS1's Scope & Standards!

