Sample UDI Labels

UDI Label Examples, HRI & Date Formatting...

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

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 Example - #2... B.Braun...

...2D/Matrix GS1 DataMatrix

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

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’acétate de sodium destinée à une utilisation
UNIQUEMENT avec apherèse 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'embalage et les
connections sont endommagés
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

Manufacturer:
B. Braun Avitum AG
34209 Melsungen
Germany

074413B

4 x 3000 ml

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US FDA UDI required
ISO 8601 date format

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 5J7

Production site:
B. Braun Avitum AG
Katterwimner Str. 32
49219 Glandorf, Germany

US Distributor:
B. Braun Medical Inc.
Bethlehem, PA 18018-3524
Made in Germany
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!