

Primary Packaging System Drawing

**Primary Packaging System number:
EMK0595**

**Primary Packaging System name:
Syringe 1 ml Long with Staked Needle and RNS**

Updated with 0.75 ml PFS for Sema Obesity project

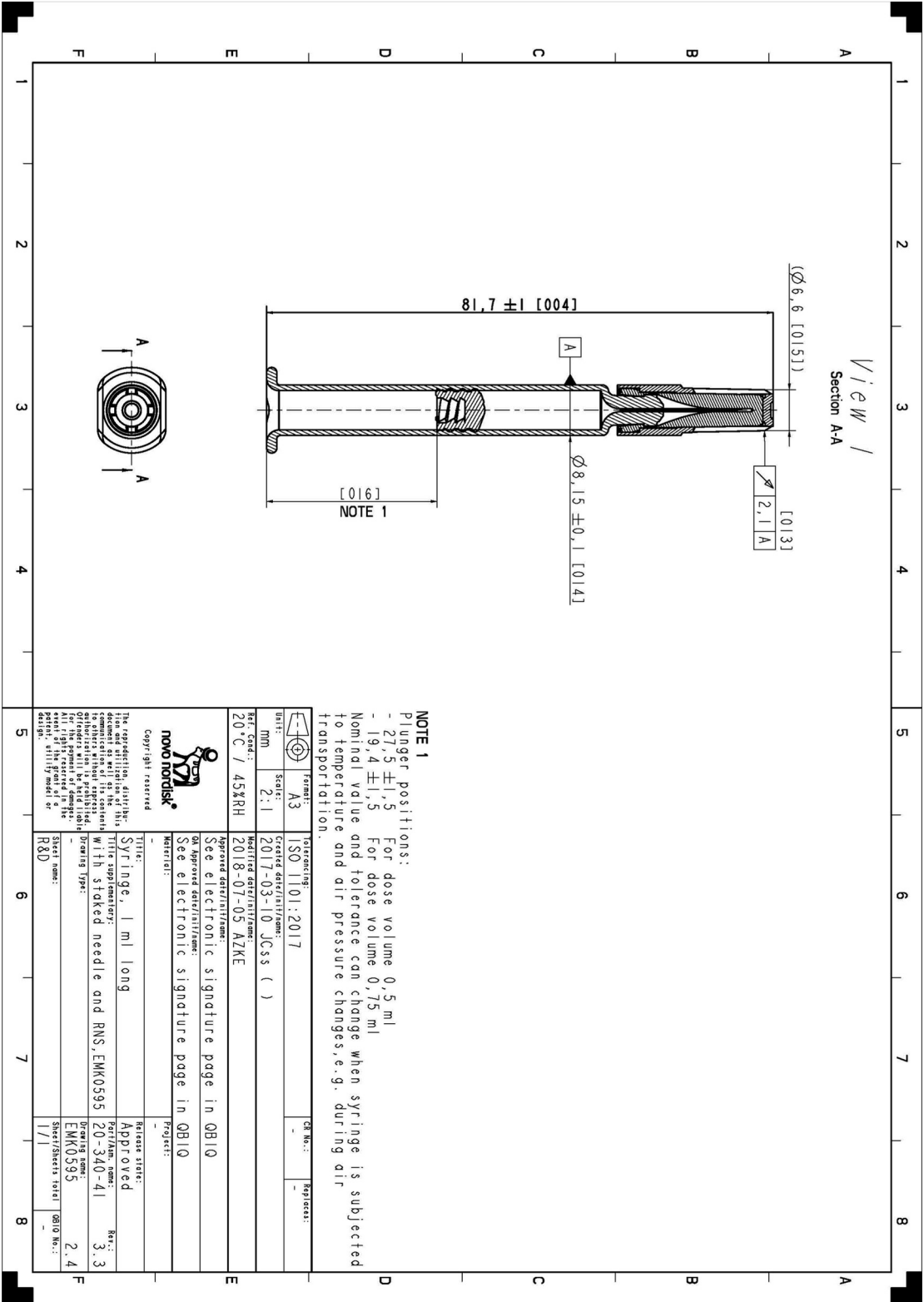
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Approvals

This document is electronically approved in NovoDOCS by the following persons or their qualified substitutes:

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FIT (Frida Thuresson)	6032, DFP QA ManDev	QA approval



Notes regarding plunger position and head space

The specified plunger position [016] is valid at time of release for the filled syringe. The plunger can move outside the specified tolerance window when the syringe is subjected to temperature and pressure changes, e.g. when the head space (amount of air in the syringe) expands during air transportation.

The head space is defined by the filling volume and plunger position at time of release. Based on the specified tolerances for filling volume and plunger position, the head space is calculated in the Tolerance Stack-up [1], [2]:

Head space volume = 0.027-0.155 ml

Head space length = 0-3.9 mm

Air transportation is considered the worst-case situation for plunger movement due to head space expansion at the lower air pressure of higher altitudes (650 mbar in aircraft with pressure cabin, corresponding to normal air pressure at an altitude of 3,500 meter). Plunger movement during air transportation is calculated in the Tolerance Stack-up [1], [2]:

Plunger movement during air transport = 0.5-2.7 mm in outwards direction

References

1. NovoDOCS 003664953, Tolerance stack-up, Syringe 1 ml Long with Staked Needle and RNS, Extractable Volume 0.5 ml, ed 3.0
2. NovoDOCS 004276288, Tolerance stack-up, Syringe 1 ml Long with Staked Needle and RNS, Extractable Volume 0.75 ml, ed 1.0

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Change log

Version	Date/Initials	Reason for revision
1.0	2018-07-18/JGJ	New document, prepared to include 0.75 ml PFS in an early phase of the DV3396 Sema Obesity SDD project, will be replaced by drawing in QBIQ later in the project.

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