Applicability

1. These Special Purchasing Conditions (Material), together with Nolato's General Purchasing Conditions and the relevant agreement and/or purchase order issued by Purchaser, set forth the terms under which the Purchaser offers to purchase Products from Seller.
2. Unless otherwise specifically stated herein, terms shall have the same meaning as in Nolato's General Purchasing Conditions.

Quality Assurance

3. Seller shall, as a minimum, maintain a Quality Management System which meets the requirements of ISO 9001, ISO 14001 and ISO 13485 and, whenever applicable, FDA CFR 21. Seller shall manufacture and test Products in accordance with the rules of the said Quality Management System.
4. Seller shall select its suppliers of intermediary products carefully and adequately monitor the same within the framework of the Quality Management System.
5. Seller shall monitor diligently and document adequately all quality assurance measures to be performed in the context of the Quality Management System. This documentation shall be retained for a period of ten years from delivery of respective Products. In justified cases and to a reasonable extent, Purchaser shall be granted access to the documentation.
6. Purchaser will evaluate the performance of Seller on a regular base and if Seller's performance is unacceptable Seller shall implement actions to improve the performance to a satisfactory level.
7. Purchaser shall to a reasonable extent support Seller adequately in the implementation of quality assurance measures. To this end, Purchaser shall in particular:

   a) provide Seller with data and information necessary for the implementation of quality assurance measures, if requested by Seller,

   b) in individual cases and for well-justified reasons make available to Seller relevant test medium and test substances.

   c) allow Seller appropriate access to Purchaser's production facilities in the case of claims for defects being asserted and enable Seller to perform an adequate on-site inspection of the particular defect, if there is reason to believe that the defect claimed is related to Purchaser's production plants or production facilities. In this case, Seller guarantees that it will observe the required rules on confidentiality. Purchaser may deny access to production processes, which are subject to confidentiality requirements, and to other trade secrets.
8. Purchaser is aware of the Regulation (EC) No. 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH). To the extent that the delivery of the Product falls within the scope of REACH, Seller will comply with all obligations under REACH.

Notification of Change

9. Seller understands that Purchaser uses the Products in the production of components of finished medical devices, pharmaceutical packaging and other areas within the Medical/Healthcare sector and complying in particular with the rules and regulations of "Current Good Manufacturing Practices (cGMP) unless otherwise stated by Purchaser.
10. Unless otherwise stated below Seller shall promptly inform Purchaser about any Modifications in accordance with applicable Notice Period.
11. "Modifications" means changes to product or Seller's production process of Product that will have a material impact on Product Specifications and Quality Requirements.
12. "Notice Period" means a period of twelve (12) months between Seller's notification to Purchaser of Modifications in writing and the date of implementation.
13. "Change Control" means a procedure to assess Modifications and that is part of the quality system of the Manufacturing Site, and that has been audited and approved by the Purchaser.
14. As minimum following "Modifications" must be considered and evaluated whether they will have impact on material:

    a) change of designated manufacturing site(s);

    b) change of designated manufacturing line(s);

    c) change of sub-supplier;

d) change of industrial process (operation processing aids);

e) change of quality control methods;

f) change of formulation of the products (composition, specification);

g) change of dimensions and tolerances;

h) change of shipping documents; and

i) change of Sellers for intermediary products.

15. In the Frame Purchase Agreement each Product should be marked if it is an Industrial, Food or a Medical/Healthcare grade.
16. For Medical/Healthcare grades Seller shall notify Purchaser in writing of any Modifications as described in section [..] and [..] with a minimum of 24 months' notice period prior to the implementation of the change. If the documentation is changed Seller shall inform Purchaser prior to the implementation of the change unless otherwise agreed for specific Products.
17. For Food grades Seller shall notify Purchaser in writing of any Modifications as described in section [..] and [..] with a minimum of three (3) months' notice period prior to the implementation of the change. If the documentation is changed Seller shall inform Purchaser prior to the implementation of the change unless otherwise agreed for specific Products.
18. For Industrial grades Purchaser wishes to get notified of any Modifications as described in section [..] and [..] without any delay.
19. Modifications that have been assessed by Seller according to its Change Control procedures at the Manufacturing Site, as having no material impact on Product Specification or Quality Requirements, do not have to be notified.

Audits and Inspections

20. To assure compliance with agreed and legal requirements Purchaser, its customer and/or third party have the right to inspect, upon reasonable notice to Seller during regular business hours, all relevant documentation, products and the facilities, which are used for production, packaging, sterilization, testing and storage. The audits are limited to processes and procedures used for manufacturing of Purchasers products, and Purchaser will see to that the obligation of secrecy is observed during the audits.
21. Seller acknowledges that notified bodies (national authorities responsible for regulation and surveillance of the development, manufacturing and marketing of drugs and other medicinal products) are entitled to make unannounced audits.