

**Your reference**Based on document - DTS
CNTS_commented B+S**Please contact**

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Offer No. A9022887-01**One Semi-automatic dosing machine - type EDM3611****Packaging material details**

The below listed packaging material is considered to be processed:

Container details

Container No.	Type of container ⁽¹⁾	Dimensions with tolerances (L x W or Ø x H, mm) ⁽¹⁾			
1 ⁽²⁾	Injection vial (T), 2 ml (DIN EN ISO 8362-1)	16,00 ^{+0.15 -0.15}	x	35,00 ^{+0.50 -0.50}	
2 ⁽²⁾	Injection vial (T), 5 ml	22,70 ^{+0.80 -0.80}	x	40,20 ^{+0.90 -0.90}	
3 ⁽²⁾	Injection vial (T), 10 ml	22,70 ^{+0.80 -0.80}	x	55,00 ^{+0.90 -0.90}	
4 ⁽²⁾	Injection vial (T), 20 ml	26,50 ^{+0.80 -0.80}	x	63,00 ^{+1.00 -1.00}	
5 ⁽²⁾	Infusion bottle, 50 ml	40,00 ^{+1.00 -1.00}	x	90,00 ^{+1.20 -1.20}	
6 ⁽²⁾	Infusion bottle, 100 ml	50,00 ^{+1.00 -1.00}	x	105,00 ^{+1.20 -1.20}	

Closure details

Closure No.	For container No. ⁽¹⁾	Type of closure ⁽¹⁾	Dimensions with tolerances (L x W or Ø x H, mm) ⁽¹⁾			
1 ⁽²⁾	1	Flip-off cap, 13 mm				
2 ⁽²⁾	2, 3, 4	Flip-off cap, 20 mm				
3 ⁽²⁾	5, 6	Flip-off cap, 34 mm				

⁽¹⁾ Please supply us with the missing technical information.⁽²⁾ Assumed values included.

**Scope of offer**

We recommend the following machinery to meet your requirements:

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01	Dosing machine - type EDM3611 (from page 2)
02	
03	
	Subtotal
50	Services at B+S (from page 14)
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Detailed description of offer items**01 Dosing machine - type EDM3611**

Item	Description
	<u>Size range:</u> Bottles diameter: min. 14,25 mm - max. 68 mm height: min. 32 mm - max. 136 mm
	<u>Set output (Ps) according to DIN EN 415-11:</u> Output depending on the operator.
	<u>Electrical supply:</u> Electrical supply is adjustable in the range of 110 V to 240 V. The electrical commissioning of the machine at Bausch + Ströbel is performed with 230/400V, 50 Hz.

01.01	Machine
01.01.01	EDM3611

Standard design

- Machine base made of aluminium.
 - Machine panels made of stainless steel (AISI 316L).
 - Electric (capacitive) two-hand control.
- Design of the machine for the following dosing system:
Dosing system for peristaltic pumps
CE mark for non European Union countries (preparation and execution of a risk assessment and integration of the resulting safety instructions in the operating manual as well as preparation of an EG Certificate of Conformity).

Item Description

Container infeed

- The containers are placed manually under the dosing position (Centering by means of adjustable prism-shaped part).

Dosing station

- Basic equipment for dosing liquid products with single-hose peristaltic pump, make Bausch + Stroebel, provision is made for operation with 1 dosing position.
 - 1 Dosing head made of stainless steel, driven by a servo motor.
 - The setting values can be entered at the operating panel of the machine and memorized separately for each size.
 - Drip retraction system for particularly critical products with the tendency to drip. The drip retraction system is provided directly by the pump movement.
 - Needle movement with bottom-up filling with the needle above level or immersed, with separate drive by servomotor. These alternatives are required to meet varying product characteristics. The specific function required can be selected at the operating panel.
 - The needle holder can be swivelled into 2 positions.
 - Hose holder for silicone hoses (each two pieces for inner diameter 0,5 mm, 0,8 mm, 1,2 mm, 1,6 mm, 2,4 mm, 3,2 mm, 4,8 mm, 6,0 mm, 8,0 mm).
- Set of dosing size parts for the single-hose peristaltic pump, 1 head, comprising:
- 1 jacket made of PEEK (autoclavable).
 - Filling hose made of silicone for one fill position, incl. hose connections.
 - 1 Filling needle made of stainless-steel AISI 316L.
 - Costs for trial runs.

Operation mode "ADVANCEDfill" with containers permanently standing on the scales, comprising:

- Start-up without product loss (fully automatic bleeding of the hoses, automatic self-optimization of the dose).
- Production without product loss (production using the settings determined during start-up, 100% IPC, continuous, automatic dose adjustment).
- Running empty with minor product loss (emptying the hoses).

Scales

- Scales to check the dosing volume, connected to the machine, comprising:
 - Laboratory balance, make Mettler Toledo.
 - Resolution 0,001 g.
 - Weighing range up to 1020 g.
 - Base frame with container centring devices (dosing takes place on the scales).

Printer

Printer to provide the batch report, separately standing, comprising:

- a) Colour laser printer (Ethernet interface of machine), make HP.

Electrical installation

- The electrical control unit is integrated into the machine.
The power is supplied via a switch cabinet (dimensions: 400 x 210 x 500 mm (L x W x H)) with main switch. The machine is connected to the switch cabinet via a power plug. The required space for the power plug is between 110 and 180 mm. The cable length from the switch cabinet to the machine is 5 meters.
- Beckhoff PLC for monitoring and control of all machine functions.
- Ethernet port for connection to customer network.
- USB port on the machine for saving logs and screenshots to a USB stick.



Item	Description	Qty.
	<ul style="list-style-type: none"> • Wire numbering. • The machine is operated from the integrated operating panel (touch panel). Functions available are: <ul style="list-style-type: none"> - Dosing volume adjustment - Dosing speed adjustment - Input of the product density - Entering the dose correction value - Recipe management - User administration - Setting the stroke, the basic position and the speed of the needle - Automatic adjustment of the dosing volume - Printing the batch report <p>All displays on operation modes, setting values and operational data appear at the operating panel.</p> <p><u>Set up for:</u></p> <p>Container No.1 Injection vial (T); 2,00 ml (16,00 x 35,00)</p>	1
01.02	<u>Equipment</u>	
01.02.01	<u>Dosing station</u>	
01.02.01.001	<p>Set of dosing size parts for the single-hose peristaltic pump, 1 head, comprising:</p> <ul style="list-style-type: none"> • 1 jacket made of PEEK (autoclavable). • Filling hose made of silicone for one fill position, incl. hose connections. • 1 Filling needle made of stainless-steel AISI 316L. • Costs for trial runs. 	3
01.02.02	<u>Scales</u>	
01.02.02.001	<p>Additional set of size parts for the scales (dosing takes place on the scales), consisting of:</p> <p>a) Container holder.</p> <p><u>Set up for:</u></p> <p>Container No.2 Injection vial (T); 5,00 ml (22,70 x 40,20)</p> <p>Container No.3 Injection vial (T); 10,00 ml (22,70 x 55,00)</p> <p>Container No.4 Injection vial (T); 20,00 ml (26,50 x 63,00)</p> <p>Container No.5 Infusion bottle; 50,00 ml (40,00 x 90,00)</p> <p>Container No.6 Infusion bottle; 100,00 ml (50,00 x 105,00)</p>	5
01.02.03	<u>Qualification / Documentation</u>	
01.02.03.001	<p>Qualification package in English language.</p> <p>The machine/line qualification provides complete verification that the machine is in compliance with the internal order and/or the valid specification.</p> <p>The qualification is based on Appendix D5 of the GAMP 5 guideline. It is further based on Annex 15 of the EU-GMP guide to Good Manufacturing Practices for Medicinal Products and the PIC/S - document PIC/S PI 006-1.</p> <p>The qualification package comprising:</p> <p>a) Qualification planning:</p> <ul style="list-style-type: none"> • Qualification Plan / Test results (TE): Verification of the personnel in charge of qualification. Test Process Sheet. Passed test section. Failed test section. 	

Item	Description	Qty.
	<p>Test incidents section.</p> <ul style="list-style-type: none"> • Test report (TR): Report with all test results. Comments on test sequences. Description of deviations and open points to be tested. Verification and release of the qualification proceedings. <p>b) Test specifications:</p> <p>IQ:</p> <ul style="list-style-type: none"> • Installation verification of the equipment (IQ-STs): Documentation verification. Mechanical installation verification. Electrical installation verification. Installation verification of the software versions. • Installation verification of the PLC system (IQ-HATS): Input and output test of the control system. PLC configuration test. <p>OQ:</p> <ul style="list-style-type: none"> • Functional verification of the system (OQ-SATS): Alarm tests. Function tests. Operating panel test. <p>c) Calibration (KAL) for all measuring systems relevant to the process:</p> <ul style="list-style-type: none"> • Description of the calibration philosophy and strategy. • Detailed description of calibration procedures. • Calibration certificates of the test devices. • Calibration protocols of individual component calibration. • Calibration protocols of measuring system calibration. <p>ci) Technical documentation (TD):</p> <ul style="list-style-type: none"> • Material specification: Declaration of compliance with the order 2.1 according to DIN EN 10204 for components integrated in media circuits in direct contact with the cleaning agent or the product under GMP aspects. • Technical data sheets: CD-ROM with data sheets of all relevant components of the control system. <p>cii) Program documentation</p> <ul style="list-style-type: none"> • Program CD with: PLC programs with comments in German or English. Operating panel program. Parameter files of control components configurable via software. <p>ciii) Qualification documentation (in blank) on CD-ROM (one copy) is included in the form of the test specification.</p> <p>civ) The qualification activities are carried out at Bausch + Ströbel.</p>	1
01.02.03.002	<p><u>Option:</u></p> <p>Functional specification (FS), including function plan.</p>	1
01.02.03.003	<p><u>Option:</u></p> <p>Software design specification, comprising:</p> <p>a) Evaluation matrix of the software.</p> <p>b) Software design description for standard modules and machine moduls.</p>	1



Item	Description	Qty.
01.02.03.004	<u>Option:</u> Hardware design specification, comprising: a) Electrical Design. b) Control system design.	1
01.02.03.005	<u>Option:</u> PID/P&ID/RI diagrams prepared according to DIN EN 62424, including detailed summary of measurement and control points.	1
01.02.03.006	<u>Option:</u> Inspection certificate 3.1 according to DIN EN 10204 for components in media circuits in direct contact with the cleaning agent or product under GMP aspects. Including traceability to the melt certificate.	1
01.02.03.007	<u>Option:</u> Documentation of the surface measurement (surface finish inspection) of available filling, gas flushing and/or closing components.	1

**50 Services at B+S**

Item	Description	Qty.
50.01	<u>General</u>	
50.01.001	Translation of the instruction manual in Romanian language.	1
50.01.002	Extension of the warranty over a period of 24 months.	1
50.01.003	<u>Option:</u> Costs for delivery of the machine(s) CIP Chisinau / Republic of Moldova - according to Incoterms 2020.	1
50.02	<u>Spare Parts Management</u>	
50.02.001	Spare Parts Package Compact. The "Spare Parts Package Compact" contains a reduced number of the most important wear parts and critical parts of the machine(s), selected by the Bausch + Ströbel Spare Parts Experts. Additional requirements, e.g. parts groups with higher priority for the customer, as well as already existing stocked parts, can be considered for the creation of the package. The corresponding information needs to be received at B+S 10 weeks ahead of FAT. All parts of the BOM are assigned to three spare part categories (wear parts, critical parts, repair parts). Further important procurement information will be provided in the included Basic Provisioning Proposal. The parts will be provided to be shipped together with the machine(s). If the "Spare Parts Package Compact" will be ordered, an additional benefit in the form of spare parts (equalling 5% of the entered package value) will be automatically added to the package.	1

**60 Services at customer**

Item	Description	Qty.
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60.01	<u>Qualification / Documentation</u>	
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60.01.001	<u>Supplementary qualification works at the user site:</u>	
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Costs for qualification for 1 Bausch + Ströbel qualification specialist(s), for the duration of 5 day(s) on your premises. The sequence of the works will be determined between manufacturer and user in a test plan. The scope is subject to the agreed time frame. The costs for travel there and back are included in the offer price. The working time at the customer's site is based on a calculation of 7.2 hours per day. Any additional hours worked will be invoiced according to our Service Terms and Conditions resp. Invoicing of Service Work.

The following tests/services are excluded :

- a) Calibrating.
- b) Air flow measurements (Sterilizing tunnel and LF).
- c) Particle measurements (Sterilizing tunnel and LF).
- d) Temperature Mappings (Sterilizing tunnel and CIP-SIP).
- e) Cleaning tests (washing machines and CIP-SIP).
- f) Siliconization tests (washing machines).

If the above mentioned tests/services are desired, they can be offered separately via our Pharma Services.

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**70 Conditions**

Item	Description	Qty.
70.01	<u>Pricing</u>	
70.01.001	<p>Prices are quoted FCA Ilshofen, by forwarding agency, uninsured - according to Incoterms 2020, as well as documentation in English language:</p> <p>a) Including</p> <ul style="list-style-type: none">• Packing.• Instruction manual<ul style="list-style-type: none">- in paper form (two copies).- on CD-ROM (two copies).• Spare parts list in electronic version on CD-ROM (one copy).• Electrical documentation<ul style="list-style-type: none">- in paper form for the control cabinet (one copy).- on CD-ROM in PDF format (two copies).• Drawings and diagrams in paper form (one copy).• Pneumatics plan on CD-ROM (if applicable) (two copies). <p>The documentation is translated using standard texts stored in our database. Any change to the standard documentation requested by the customer has to be checked and the translation will be subject to a surcharge. For preparation of the design and test specifications, the standard documents of the manufacturer will be used. Changes to the content can be made once and after consultation and with the consent of the manufacturer only.</p> <p>b) Excluding</p> <ul style="list-style-type: none">• Installation.• Commissioning.	
70.01.002	<p><u>Capacity particulars:</u></p> <p>The capacity indicated is the theoretical capacity per unit of time that can be obtained with set operational speed, uninterrupted operation and constant supply of containers.</p> <p>However, according to the type of machine it is especially dependent upon the type of closure, packaging material, auxiliary packaging material, upon the type, characteristics and metered quantity of product, as well as the operating conditions.</p>	
70.04	<u>Other/General conditions</u>	
70.04.001	The warranty period will be 36 months from passing of the risk.	
70.04.002	Country of origin: Federal Republic of Germany	

Item	Description	Qty.
70.04.003	<p>Bausch + Ströbel standard documentation for the above mentioned equipment:</p> <p>a) Documents as paper print-out</p> <ul style="list-style-type: none"> • Machine instruction manual (two copies). • Electrical documentation, wiring diagram (one copy). • EC Declaration of Conformity for machines with CE marking (one copy). <p>b) Drawings / Diagrams as print-out or as file (each one copy)</p> <ul style="list-style-type: none"> • Layout drawing. • Cable layout plan (if necessary). • Cleaning schematic (for cleaning machines). • Media connection plan (for cleaning machines). • Flow schematic (air flow plan) (for sterilizing tunnels). • Partition wall drawing (for sterilizing tunnels). • CIP-SIP schematic and valve position plan (if necessary). <p>c) Documents on data carrier</p> <ul style="list-style-type: none"> • Machine instruction manual as PDF (two copies). • Instruction manuals for installed purchased parts as PDF - generally in German, English and French (two copies). • Data sheets of all the recommended lubricants as PDF (two copies). • Technical documents (pneumatic circuit diagram, gas-flushing circuit diagram, fuel gas / oxygen circuit diagram) as PDF - depending on machine type and equipment (two copies): • Electrical documentation, wiring diagram as PDF (two copies) • Spare part list (one copy). • Interactive spare part catalog (one copy). <p><u>Note:</u> Our operating instructions are drawn up according to the requirements of EN 62079 and EN ISO 12100 as well as 2006/42/EG (for machines with CE marking).</p>	



80. Other Commercial and Legal Provisions

I.

Retention of Title

The property in the delivered products shall not pass to the Buyer until Bausch + Ströbel has received payment in full of the purchase price.

II.

Warranty

Bausch + Ströbel warrants that the products delivered will be free from defects in materials and workmanship. Defective parts shall be repaired or replaced by Bausch + Ströbel at its discretion.

Bausch + Ströbel's liability is limited to defects, which appear within the warranty period.

Bausch + Ströbel is not liable for defects in or damage to the delivered products which are due to inappropriate or improper use, improper interference or repair work on the part of the Buyer or third parties, normal wear and tear, faulty or careless handling or improper maintenance of the delivered products, use of unsuitable operating materials/substitute materials, defective construction work, chemical, electrochemical or electrical influences, as far as Bausch + Ströbel is not responsible for the occurrence of the event causing the defect or damage.

III.

Liability for Damages

Bausch + Ströbel shall only be liable for damages resulting from negligence or wilful misconduct on the part of Bausch + Ströbel.

The total amount of damages is limited to the delivery value. To the extent legally permissible and subject to the Buyer's right to claim liquidated damages in case of late delivery Bausch + Ströbel's liability, irrespective on what legal basis, for indirect and consequential damages (including, without limitation, lost profits, loss of goodwill, losses arising out of a business interruption and frustrated expenses) shall be excluded.

This limitation of liability will not apply in the event of wilful misconduct. Also the legal liability for culpable damage to life, body and health shall remain unaffected.

IV.

Late delivery

In case of late delivery solely attributable to Bausch + Ströbel, and provided that the Buyer has suffered damage owing to the delay, it may claim liquidated damages. The total amount of damages for late delivery is limited to 0.5% of the respective delivery value for each full week of delay, up to a maximum of 5% of the respective delivery value. Any further damage claims because of delay are excluded.

V.

Intellectual Property

All of Bausch + Ströbel's intellectual property in, and relating to the products and services, including inventions, patents, trademarks, copyright, know-how, drawings, designs, trade secrets and other proprietary rights or forms of intellectual property, and any alterations, additions or amendments to the intellectual property shall remain the exclusive property of Bausch + Ströbel, and may not, without Bausch + Ströbel's consent, be made available to third parties. With regard to such intellectual property Bausch + Ströbel grants to the Buyer without limitation in time or place a non-exclusive right of use subject to the terms of the Contract.