



INNOVATION

APPLICATION

FORMATION

CARACTERISATION

8, allée Geoffroy Saint Hilaire
CS30021
F-33615 PESSAC Cedex
Tél : (33) 05 47 74 69 00
Fax : (33) 05 47 74 80 13

Mél : rescoll@rescoll.fr
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Agréments formation

72330571433 DRTEFP Aquitaine
EWF – Certificat n° 27 pour
EAB-EWF 515
EAS-EWF 516

SIRET 437 950 173 00041 – NAF 7490B – VAT FR 81437950173

AO 2014/007

→ Name et adresse de l'organisme acheteur :

RESCOLL, Société de recherche,
8 Allée Geoffroy Saint Hilaire CS 30021
33615 PESSAC, FRANCE
Tel : +33.5.47.74.69.00
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Contacts :

Commercial : Konstantin SIPOS : konstantin.sipos@rescoll.fr
Technique : Marilys Blanchy marilys.blanchy@rescoll.fr

→ Scope of the offer

Acquisition of an electrospinning equipment for medical devices applications

→ Main characteristics :

An electrospinning apparatus which typically be used for producing medical devices based on polymers solution of high viscosity either synthetic polymer or natural ones.

Technical specifications:

Thus apparatus will have the following specifications:

- To be lab bench equipment
- Temperature (+/- 1°C) and humidity (+/- 5% Hr) controlled chamber
- Exhaust system
- Easy cleaning (rounded angles, dismountable of pieces, cleanable surfaces)
- Safe by design: avoid moisture and dust accumulation, manufacturing materials of the equipment that might be in contact with the polymers or might pollute them must be compliant with the Medical Devices regulations).
- All materials used for the equipment should be GMP compliant and be adequate for a qualification of manufacturing process (IQ, OQ, PQ) according to ISO 13485
- Be composed of emitter from single jet to, multiple jets and high throughput jet
- Possibility to develop custom-made collector for complex shape (collector clamping zone cad file must be provided)
- Monitoring of data



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- Saving of data in an embedded memory.
- Ability to send data to the company network through and classic Ethernet connection (IP address and RG45 plug).
- Data files must be in a .csv format or excel readable format.
- To be provided with full safety especially regarding high voltage discharge and opening
- Monitoring Touch panel
- Voltage : 0-20kV at least
- Collector : Drum collector in stainless steel or Titanium with a rotating speed from 10 to at least 2000rpm

Documentation:

- Description of the installation, certificate of calibration of monitoring point toward a qualification of the line. Including but not limited to :
 - FDS (Functional Design Specification)
 - Complete parts lists
 - Material certificates for all product contact parts
 - Surface roughness measurements for all product contact parts
 - Wiring diagram
 - Instrument calibration documentation
- Documentary system for the IQ, OQ, PQ qualification

Maintenance:

Hotline and online maintenance availability

List of non-standard (custom made) spare parts and their respective costs

The provided software must be upgraded free of charges during the warranty period of 2 years

Quote should include :

- Detailed quote for each accessory and the device
- Price must be CIF.
- Unloading, unpacking, set up
- Support for IQ and OQ on site at Rescoll
- Equipment Induction/training on site at Rescoll
- Warranty:

A guarantee of minimum 2 years and specify conditions of payment



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→ Criteria for the bid

The most advantageous offer commercially speaking will be appreciated according to the following with their weighting

1. Technical criteria : 40 % ;
2. Price : 50 % ;
3. After sales services and technical assistance : 10 %.



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