Terms and Conditions of Supply

Project Name: **"2022 COVID-19 Response Mechanism Additional Funding for Moldova"**

Purchaser: **Public Institution "Coordination, Implementation, and Monitoring Unit of the Health System Projects"**

Consignee: **IFP "Chiril Draganiuc" – National Reference Laboratory (Chisinau).**

Package No: **117/GD/RM**

1. Prices and Schedules for Supply

The Supplier acknowledges that he will also be responsible for:

a) Delivery of the goods to the consignee addresses (Chisinau).

LOT 1. "Disposable FFP2/N95 NR Filtering half Mask with Exhalation Valve (Particulate respirators)":

№	Item	Quantity	Unit Price Chisinau, *MDL*	Total Price Chisinau, MDL	Delivery Time	Consignee
1	**Disposable FFP2/N95 NR Filtering half Mask with Exhalation Valve (Particulate respirators), to protect against particles**	**5200 pieces**	**24.75**	**128 700.00**	10 calendar days	**IFP (Chisinau).**
			TOTAL:	**128 700.00**		

Note: *In case of discrepancy between the unit price and total derived from unit price, the correction will be done as provided in Paragraph 9 (iii) of the Invitation to quote*

2. Fixed Price: The prices indicated above are firm and fixed and not subject to any adjustment during contract performance. We are confirming that the prices do not include the customs duties, excise duty, custom procedures tax, and Value Added Tax (VAT) in Moldova.

3. Country of Origin: The goods offered should have their origin in World Bank member countries, and you will be required to furnish a certificate of origin for each item.

4. Delivery Schedule: The delivery should be completed as per delivery conditions from the Terms and Conditions of Supply from the date of signing of the contract.

5. Applicable Law: The Contract shall be interpreted under the laws of the Purchaser's country.

6. Resolution of Disputes: The Purchaser and the Supplier shall make every effort to resolve amicably by direct informal negotiation any disagreement or dispute between them under or in connection with the Contract. In the case of a dispute between the Purchaser and the Supplier, the dispute shall be settled by the provisions of the laws of the Purchaser's country.

7. Delivery and Documents: Upon shipment, the Supplier shall notify the Purchaser by cable or fax of the full details of the shipment, including contract number, description of goods, quantity, etc.

8. Payment for your invoice will be made 100% against delivery of goods, by bank transfer in favor of the Supplier's Bank, within ten (10) days from receipt of the goods, and related services as provided by paragraph 1 of these Terms and Conditions of supply (hereinafter referred to as the "Related Services"), and a final acceptance document for goods and related services issued by the Purchaser and confirmed by the Consignee (hereinafter referred to as the "Final Acceptance Document").

9. Warranty: The goods offered should be covered by the manufacturer's warranty (shelf life) as indicated in Annex A to Terms and Conditions of supply from the date of the Final Acceptance Document. **Please specify the warranty period and terms in detail according to Annex A requirements.**

10. Manufacturer's Authorization. The Purchaser can require the Supplier before awarding the contract to provide the Manufacturer's Authorization for the goods.

11. Packaging and Marking Instructions: The Supplier shall provide standard packing of the Goods as required preventing their damage or deterioration during transit to their final destination, as indicated in the Contract.

12. Defects: All defects will be corrected by the Supplier without any cost to the Purchaser within 30 days from the date of notice by the Purchaser.

13. Force-Majeure: The supplier shall not be liable for penalties or termination for default if and to the extent that its delay in performance or other failures to perform its obligations under the Contract is the result of an event of Force-Majeure.

For purposes of this clause, "Force-Majeure" means events beyond the control of the Supplier and do not involve the Supplier's fault or negligence and are not foreseeable. Such events may include, but are not restricted to, the act of Purchaser in its sovereign capacity, wars or revolutions, fires, floods, epidemics, quarantine restrictions, and freight embargoes.
If a Force-Majeure situation arises, the Supplier shall promptly notify the Purchaser in writing of such condition and the cause thereof. Unless otherwise directed by the Purchaser in writing, the Supplier shall continue to perform its obligations under the Contract as far as is reasonably practical and shall seek all reasonable alternative means for performance not prevented by Force-Majeure event.

14. Required Technical Specifications

(i) General Description

a. All goods must be new, unused, of the most recent and current models, incorporating all recent improvements in design and materials, unless otherwise provided for in these specifications.

(ii) Specific details and technical standards - as per Annex A to Terms and Conditions of Supply

The supplier confirms compliance with the above specifications ***(In case of deviations supplier to list all such deviations)***

15. Failure to Perform: The Purchaser may cancel the Contract if the Supplier fails to deliver the goods and provide Related Services, following the above terms and conditions, despite a 10-day notice given by the Purchaser, without incurring any liability to the Supplier.

16. Delays: If the Supplier fails to deliver any or all of the goods by the date of delivery or perform the Related Services within the period specified in the Contract (as provided by the Delivery schedule above), the Purchaser may without prejudice to all its other remedies under the Contract, deduct from the Contract Price, as liquidated damages, a sum equivalent to the percentage of 0.1% of the delivered price of the delayed goods or unperformed services for each working day or part thereof of delay until actual delivery or performance, up to a maximum deduction of the percentage of ten (10)% of the contract price.

17. Fraud and Corruption: It is the Global Fund's policy to require that all bidders, suppliers, and contractors and their agents (whether declared or not), personnel, subcontractors, sub-consultants, service providers, and suppliers under Global Fund-financed contracts observe the highest standard of ethics during the procurement and execution of such contracts.[1] Under these circumstances, the Global Fund has developed a **Code of Conduct for Suppliers** which is aimed to ensure that Suppliers and Suppliers' Representatives will participate in the procurement process in a manner that is transparent, fair, accountable, and honest, including by complying with all applicable laws and regulations regarding fair competition as well as recognized standards of good procurement practice. The detailed document (Code of Conduct for Suppliers) can be found and must be read on the website: https://www.theglobalfund.org/en/governance-policies/

18. As a bidder, we hereby confirm that we have read the Code of Conduct for Suppliers as stated in clause 17 above, and by our below signature we assume the responsibility for the actions taken by us within this procurement.

NAME OF SUPPLIER **"ENDO–CHIRURGIE" SRL**

Authorized Signature and Stamp _____

Place: **REPUBLICA MOLDOVA, CHIŞINĂU** Date: 12.08.2022

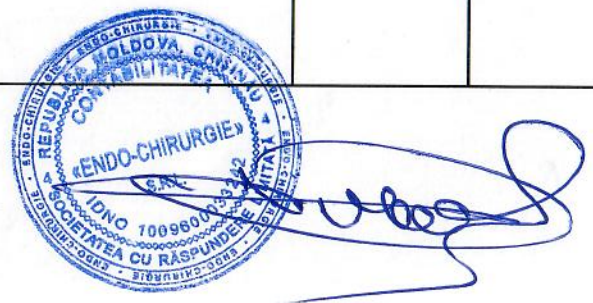
[1] *In this context, any action taken by a bidder, supplier, contractor, or any of its personnel, agents, subcontractors, sub-consultants, service providers, suppliers and/or their employees to influence the procurement process or contract execution for undue advantage is improper.*

to Terms and Conditions of supply

Specific details and technical standards

LOT: "Disposable FFP2/N95 NR Filtering half Mask with Exhalation Valve (Particulate respirators), to protect against particles for the National Reference Laboratory in TB Microbiology"

№	Name of product	Minimal technical requirements	Total Quantity	Packing	Manufacturer (name, country); Model number; Description; Compliance
1	**Disposable FFP2/N95 NR Filtering half Mask with Exhalation Valve, (Particulate respirators), to protect against particles.**	• To be used for medical purposes for the protection of personnel working in Tuberculosis laboratories; • Can help protect against airborne micro-organisms such as mycobacterium tuberculosis, and SARS; • Stretchable **headbands** easy to put on and provide a secure fit; • Adjustable nose clip; • Protection Level – FFP2 (N95); minimum 94-95% according to "Chapter 7.2, WHO Tuberculosis Laboratory Biosafety Manual. (the Year 2012)". • Assigned Protection Factor - min. 10; • Includes an exhalation valve fitted to the front of the respirator which minimizes heat and moisture build-up. • **At least 3 samples of the offered product to conduct Fit Test (sealing property test). Will be considered only the products that pass the Fit Test.**	5200 pcs.	20 pcs/pack	**Halyard Health , USA, 62360** Reference 62360: TECNOL* PFR P3 Filtering Half Mask with valve/White Pouch-Style with Elastic Headbands and Valve, Respirator Face Mask Dimensions Width: 20 cm Height: 8.7 cm Headbands: 56 cm circumference Exhalation valve: 4.1 cm diameter Nosepiece: 9 cm length Properties Type FFP3 NR mask as defined by EN 149 Does not contain Natural Rubber Latex. Does not contain DEHP. Outside layer: Polypropylene, white Middle layer: Respirator Filter Media (polypropylene melt blown) Inside: Polypropylene, white Nose piece: Polyethylene Coated Steel Wire Headbands: Synthetic Rubber Valve: polypropylene housing and synthetic rubber



	Mandatory requirements (this certificates/letters must be included in the offer)	• Manufacturer's ISO 9001 certificate; • CE standard EN149:2001+A1:2009; • Written confirmation (certificate) that the offered products are intended for use in Tuberculosis laboratories; • All presented certificates should be valid; • Original manufacturer packing for all items; • Each product packed individually; • Warranty: the remaining shelf life should be not less than 80% from the total one. • VALIDITY OF THE OFFER: Quotation is valid for **forty-five (45) calendar days** from the deadline for receipt of the quotation indicated in Paragraph 5 of the Invitation to Quote.

- **All goods will be tested by the beneficiary. The goods will be accepted and the acts of receipt will be signed upon positive testing performed by the beneficiary.**

NAME OF SUPPLIER **"ENDO–CHIRURGIE" SRL** Authorized Signature and Stamp _____

Place: **REPUBLICA MOLDOVA, CHIŞINĂU** Date: 12.08.2022

"Endo-Chirurgie" S.R.L.
Codul fiscal: 1009600033242
Adresa postală: mun.Chișinău, str. Meșterul Manole, nr. 9.
Telefon/Fax: (022) 23-21-33, (022) 66-72-86

ENDO CHIRURGIE

ORDIN nr. 25

„De împuternicire a persoanei"

Din 01 septembrie 2020

Întru desfășurarea continuă și corectă a procesului de întocmire a documentelor pentru participarea în cadrul procedurilor de achiziții publice, organizate de către Autoritățile Contractante din Republica Moldova, în cazul absenței mele de la locul de lucru,

ORDON:

A împuternici dl **DUBALARI Pavel**, IDNP: **2001003326049**, angajat în calitate de jurisconsult, pentru ca în numele meu să:

1. Semneze oferta, precum și toate actele aferente procedurilor de achiziții, inclusiv prin aplicarea semnăturii sale electronice (digitală).
2. În caz de necesitate va aplica ștampila pe actele menționte mai sus.

Director „Endo-Chirurgie" S.R.L. **GHEREG Victor**

Luat la cunoștință **DUBALARI Pavel**

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea cu Răspundere Limitată

"ENDO-CHIRURGIE"

ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de identificare de stat - codul fiscal

1009600033242

Data înregistrării **24.09.2009**

Data eliberării **24.09.2009**

Jimbei Mihai, registrator

Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

MD 0097512

I.P. "AGENŢIA SERVICII PUBLICE"
Departamentul înregistrare şi licenţiere a unităţilor de drept

EXTRAS
din Registrul de stat al persoanelor juridice

nr. **8732** din **02.06.2022**

Denumirea completă: **Societatea cu Răspundere Limitată «ENDO-CHIRURGIE».**
Denumirea prescurtată: **«ENDO-CHIRURGIE» S.R.L.**
Forma juridică de organizare: **Societate cu Răspundere Limitată.**
Numărul de identificare de stat şi codul fiscal: **1009600033242.**
Data înregistrării de stat: **24.09.2009.**
Sediul: **MD-2021, str. Drumul Viilor, 30/2, ap. 54, mun.Chişinău, Republica Moldova.**
Modul de constituire: **nou creată.**
Obiectul principal de activitate:
1 Acordarea asistenţei medicale de către instituţiile medico-sanitare private;
2 Activitatea farmaceutică;
3 Importul, fabricarea, comercializarea, asistenţa tehnică şi (sau) reparaţia dispozitivelor medicale şi (sau) a opticii;
4 Comerţul cu amănuntul al articolelor medicale şi ortopedice;
5 Comerţul cu amănuntul al produselor cosmetice şi de parfumerie, articolelor de toaletă;
6 Alte activităţi de asistenţă medicală;
7 Activităţi de întreţinere corporală;
8 Activităţi de consultare pentru afaceri şi management;
9 Activităţi de cercetare a pieţei şi de sondaj al opiniei publice;
10 Importul şi (sau) fabricarea, depozitarea, comercializarea angro a substanţelor şi materialelor chimice, toxice, articolelor şi produselor chimice de menaj;
11 Importul şi (sau) depozitarea, comercializarea produselor de uz fitosanitar şi (sau) a fertilizanţilor.
Capitalul social: **1132300** lei.
Administrator: GHEREG VICTOR, IDNP 2003001030201,
Asociat şi Beneficiar efectiv:
1. GHEREG VICTOR , IDNP 2003001030201
cota 1132300.00 lei, ce constituie 100 %.

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de: 02.06.2022.

Specialist coordonator
tel. 022-207837

Frantuz Marina

EB 0409392

Date cu caracter personal

EC Quality of production by means of monitoring

This is to certify that:

Halyard Healthcare Inc
5405 Windward Parkway
Alpharetta
Georgia
30004-3894
USA

Holds Certificate Number:

CE 628494

In respect of:
The manufacture of respirators to EN 149:2001+A1:2009
See continuation sheet for details.

On the basis of our examination, under the requirements of Council Directive 89/686/EEC "Personal Protective Equipment" Article 11B, system for ensuring EC quality of production by means of monitoring.

For and on behalf of BSI,
a Notified Body for the above Directive
(Notified Body Number 0086):

Gary Fenton, Global Assurance Director

First issued: 9/01/2015

Latest Issue: 9/01/2015

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EC Quality of production by means of monitoring

No. CE 628494

Product manufactured at the following location:

LA Ada De Acuna, S, de R.L de C.V
Km. 4.5 Carr. Presa La Amistad
Ciudad De. Acuna
Coahuila
26220
Mexico

Product Specification

The products covered by the scope of this Article 11B certificate conform to the following PPE devices and referenced standard.

Product Type	Basis of Product Assessment
Respiratory protective devices - Filtering half masks to protect against particles	EN 149:2001+A1:2009

Certificate Administration Details

Certificate amendment and related confidential BSI report record:

Issue date	Comments	BSI Report No.
January 2015	First issue, traceable to BSI certificate CE 01449.	0086:14:8266769

First issued: 9/01/2015 Latest Issue: 9/01/2015

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

O & M Halyard, Inc.
9120 Lockwood Blvd
Mechanicsville
Virginia
23116
USA

Holds Certificate No: **FM 697013**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design and development, manufacture and distribution of surgical gowns, protective garments, face masks, surgical drapes, orthopedic soft goods, patient care products, cold therapy products, C-Section packs, OB Packs, orthopedic packs, sterile and non-sterile examination gloves, Temperature management systems for the areas of general surgery and general medical use and sterilization wrap and non-woven materials for medical devices.

Gary C Slack

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2014-12-09
Latest Revision Date: 2020-01-08

Effective Date: 2020-01-09
Expiry Date: 2023-01-08

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REPUBLICA MOLDOVA, CHISINAU, CONTABILITATEA, «ENDO-CHIRURGIE» S.R.L., IDNO 1009600033242, SOCIETATEA CU RASPUNDERE LIMITATA

Certificate No: **FM 697013**

Location	Registered Activities
O & M Halyard, Inc. 9120 Lockwood Blvd Mechanicsville Virginia 23116 USA	Headquarter management activities.
O & M Halyard, Inc. 5405 Windward Parkway Alpharetta Georgia 30004 USA	The design and development of surgical gowns, protective garments, face masks, surgical drapes, orthopedic soft goods, patient care products, cold therapy products, C-Section packs, OB Packs, orthopedic packs, sterile and non-sterile examination gloves, Temperature management systems for the areas of general surgery and general medical use and sterilization wrap and non-woven materials for medical devices.
Halyard North Carolina, LLC 389 Clyde Fitzgerald Rd. Linwood North Carolina 27299 USA	The manufacture of nonwoven materials for medical devices, Sterilization wrap, and infection control products including disposable gowns and linens.
La Ada de Acuna 14 Finegan Road Del Rio Texas 78840 USA	Receiving and Incoming Inspection, Warehouse and Distribution.
O&M Halyard Honduras S.A. de C.V. Carretera Tegucigalpa Villanueva Cortes Honduras	The manufacture and distribution of disposable sterile and non-sterile surgical gowns.
La Ada de Acuna Avenida Hidalgo #16 Parque Industrial San Carlos Nogales Sonora 84092 Mexico	Receiving and incoming inspection. Manufacturer/Conversion of nonwoven materials.

Original Registration Date: 2014-12-09
Latest Revision Date: 2020-01-08

Effective Date: 2020-01-09
Expiry Date: 2023-01-08

Certificate No: **FM 697013**

Location	Registered Activities
La Ada de Acuna Kim. 4.5 Carreterra Presa La Amistad Ciudad De Acuna Coahuila 26220 Mexico	The manufacture of non-sterile face masks (surgical isolation, industrial and respirator), non-surgical gowns, cold therapy products, and sterilization wrap.
La Ada de Acuna S.De. R.L. De C.V AV. Hidalgo #6 Esq., Blvd., Luis Donaldo Colosio, Col. Educativa Nogales Sonora 84093 Mexico	The manufacture of disposable products including sterile and non sterile surgical packs, gowns and components. The manufacture of temperature management systems for areas of general surgery.
Safeskin Medical & Scientific (Thailand) Ltd. 200 Moo 8, Kanchanavanich Road, Tambol Prik, Amphur Sadao, Songkhla 90120 Thailand	The design and development, production and distribution of industrial gloves, sterile and non-sterile examination gloves.

Original Registration Date: 2014-12-09
Latest Revision Date: 2020-01-08

Effective Date: 2020-01-09
Expiry Date: 2023-01-08

bsi.

By Royal Charter

Conformity to Type based on Quality Assurance of the Production Process

This is to certify that:

O&M Halyard Inc.
9120 Lockwood Blvd
Mechanicsville
Virginia
23116
USA

Holds Certificate Number: CE 711886

In respect of:

The manufacture of filtering half masks to EN 149:2001+A1:2009.

on the basis that BSI carried out the quality assurance assessment under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex VIII (Module D)

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Drs. Dave Hagenaars, Managing Director

Previous Notified Body: BSI 0086

First Issued: 2019-10-11

Latest Issue: 2019-10-11

Effective Date: 2019-10-11

Expiry Date: 2024-10-11

PRODUCTS
RvA C 646

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Conformity to Type based on Quality Assurance of the Production Process

No. CE 711886

Product manufactured at the following location:

LA Ada De Acuna, S, de R.L de C.V
Km. 4.5 Carr. Presa La Amistad
Ciudad De. Acuna
Coahuila
26220
Mexico

Product Specification

The products covered by the scope of this Certificate conform to the following standard:

Standard	Product Type
EN 149:2001+A1:2009	Respiratory protective devices - Filtering half masks to protect against particles

Certificate Amendment Record

Issue date	Comments	BSI Project No.
October 2019	First issue under PPE Regulation (EU) 2016/425.	2797:19:9775112

Certificate validity

The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspects of the overall quality system utilized in the manufacture of the products, failure to do so could invalidate the Certificate in respect of product manufactured after the introduction of such changes.

First Issued: 2019-10-11
Latest Issue: 2019-10-11

Effective Date: 2019-10-11
Expiry Date: 2024-10-11

HALYARD

TECNOL* PFR P3

Filtering Half Mask with Valve

TECHNICAL DATA SHEET

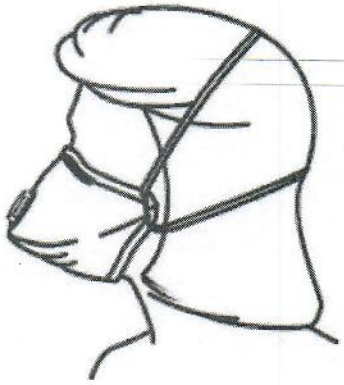
CE

Description

Reference
62360: TECNOL* PFR P3 Filtering Half Mask with valve/White Pouch-Style with Elastic Headbands and Valve, Respirator Face Mask.

Dimensions
Width: 20 cm
Height: 8.7 cm
Headbands: 56 cm circumference
Exhalation valve: 4.1 cm diameter
Nosepiece: 9 cm length

Properties
Type FFP3 NR mask as defined by EN 149.



Intended Use

To be used for single shift/maximum 8 hours.
These masks are to be used against solid and liquid aerosols only
See instruction for use for important additional warnings.

Main Materials

Does not contain Natural Rubber Latex. Does not contain DEHP.
Outside layer: Polypropylene, white
Middle layer: Respirator Filter Media (polypropylene melt blown)
Inside: Polypropylene, white
Nose piece: Polyethylene Coated Steel Wire
Headbands: Synthetic Rubber
Valve: polypropylene housing and synthetic rubber

Sterilisation

These products are non-sterile.
These products cannot be sterilized.

Packaging

Shipping case of 240 units.
20 units are placed within 1 dispenser and 12 dispensers are placed within a shipping case.
Bar coding: GS1-128 on shipping case and dispenser boxes.

Manufacturing

Product is manufactured in China.

Regulatory Information

Product CE marked as per 89/686/EEC Directive on Personal Protective Equipment.
Classification: PPE Category III.
Product compliant with EN 149:2001+A1:2009, EN143:2005.

Storage Information

Store in a dry and cool place, away from sources of light and radiation.
Keep the masks as much as practicably possible in their dispenser box.
Keep dispenser boxes as much as practicably possible in their shipper box.

Shelf Life

5 years, from date of manufacture.

REPUBLICA MOLDOVA, CHISINAU, CONTABILITATEA «ENDO-CHIRURGIE» S.R.L. IDNO 1009600033242 SOCIETATEA CU RASPUNDERE LIMITATA

Created 31-Mar-2015, version 0

The dimensions and properties listed above can vary within pre-established specifications. This document was created using the most recent information. In the interest of continuous improvement, the characteristics of the product may change without prior notice.

HALYARD

EC Declaration of Conformity

Name of Products:	Filtering Half Mask
Product Codes:	62354 (PFR P1 Filtering Half Mask) 62408 (PFR P2 Filtering Half Mask) 62360 (PFR P3 Filtering Half Mask)
Legal Manufacturer (Place of Issue):	Halyard Health, Inc. 5405 Windward Parkway Alpharetta, Georgia (GA) 30004, USA
EU Authorized Representative:	Halyard Belgium BVBA Leonardo Da Vincilaan 1 1930 Zaventem Belgium
Product Standards:	EN 149:2001+A1:2009 (for FFP1, FFP2, FFP3)
Device Classification:	PPE Category III
CE certificate number:	CE 628494
Notified Body:	BSI (0086)
Quality Management System:	FM 620884 (BSI)

I, the undersigned, hereby declare that the new Personal Protective Equipment (PPE)(s) specified as above meet(s) the applicable provisions of European Council Directive 89/686/EEC and with the Essential Requirements of Annex II (Basic Health and Safety Requirements).

These products are identifical to the PPE(s) which is the subject of EC Quality of production by means of monitoring Certificate No. 628494 issued by BSI (0086). These products are subject to the procedure set out in Article 11 point B of Directive 89/686/EEC under the supervision of the notified body BSI (0086).

All supporting documentation that contains proof of compliance to Annex III for PPE models referenced in Article 8 (2) of the aforementioned Directive(s) is retained under the premises of Halyard Health, Inc. This declaration applies to all of the above specified products from the signature date forward.

Authorized Signature:

Name: Katy Johnson
Title: Regulatory Affairs Technical Leader
Halyard Health, Inc.
Date: 03-Nov-2015