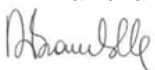

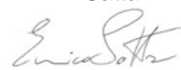


DOCUMENT TITLE:

**LIST OF INSPECTION ACTIVITIES INCLUDED
IN THE FLEXIBLE SCOPE**

REVISION HISTORY

REV	DATE	ISSUED BY	REVIEWED BY	APPROVED BY
00	18 July 2024	D. Brambilla	C. Bruseghini	E. Satta
01	11 September 2024	D. Brambilla 	C. Bruseghini 	E. Satta 

Field	Range	Stage	Requirements
- Agricoltura, prodotti alimentari e loro derivati	- Ispezione documentale - Ispezione Visiva - Ispezione sulla produzione/processo	- Produzione - Collaudo - Pre-spedizione - Carico - Scarico - Post-Spedizione	<ul style="list-style-type: none"> • Proc. SDP 11 rev. 06 • ISO 2859-1:2007 - Sampling procedure for inspection by attributes - Part 1: Sampling scheme indexed by acceptance quality limit (AQL) for lot-by-lot inspection • US F&DA Investigations Operations Manual - Ed.2021 • EU Directive 2014/32 - Harmonization of the Laws of the Member States relating to the making available on the Market of Measuring Instruments • EU Directive 2014/31 - Harmonization of the Laws of the Member States relating to the making available on the Market of Non-Automatic Weighing Instruments • Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs • Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin • ANSI/ASQ Z1.4-2003 (R2018): Sampling Procedures and

			<p>Tables for Inspection by Attributes</p> <ul style="list-style-type: none"> • Specifiche del Cliente
- Prodotti industriali	<ul style="list-style-type: none"> - Ispezione documentale - Ispezione Visiva - Ispezione sulla produzione/processo 	<ul style="list-style-type: none"> - Produzione - Collaudo - Pre-spedizione - Carico - Scarico - Post-Spedizione 	<ul style="list-style-type: none"> • Proc. SDP 11 rev. 06 • ISO 2859-1:2007 - Sampling procedure for inspection by attributes - Part 1: Sampling scheme indexed by acceptance quality limit (AQL) for lot-by-lot inspection • US F&DA Investigations Operations Manual - Ed.2021 • EU Directive 2014/32 - Harmonization of the Laws of the Member States relating to the making available on the Market of Measuring Instruments • EU Directive 2014/31 - Harmonization of the Laws of the Member States relating to the making available on the Market of Non-Automatic Weighing Instruments • ISO 8015:2011 Geometrical product specifications (GPS) Fundamentals Concepts, principles and rules • ANSI/ASQ Z1.4-2003 (R2018): Sampling Procedures and Tables for Inspection by Attributes • Specifiche del Cliente

<ul style="list-style-type: none"> - Prodotti medicinali e cosmetici 	<ul style="list-style-type: none"> - Ispezione documentale - Ispezione Visiva - Ispezione sulla produzione/processo 	<ul style="list-style-type: none"> - Produzione - Collaudo - Pre-spedizione - Carico - Scarico - Post-Spedizione 	<ul style="list-style-type: none"> • Proc. SDP 11 rev. 06 • ISO 2859-1:2007 - Sampling procedure for inspection by attributes - Part 1: Sampling scheme indexed by acceptance quality limit (AQL) for lot-by-lot inspection • US F&DA Investigations Operations Manual - Ed.2021 • EU Directive 2014/32 - Harmonization of the Laws of the Member States relating to the making available on the Market of Measuring Instruments • EU Directive 2014/31 - Harmonization of the Laws of the Member States relating to the making available on the Market of Non-Automatic Weighing Instruments • Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast) • ISO 15378:2017 Primary packaging materials for medicinal products • ANSI/ASQ Z1.4-2003 (R2018): Sampling Procedures and Tables for Inspection by Attributes • Specifiche del Cliente
<ul style="list-style-type: none"> - Materie prime secondarie e scarti di lavorazione 	<ul style="list-style-type: none"> - Ispezione documentale - Ispezione Visiva 	<ul style="list-style-type: none"> - Produzione - Collaudo 	<ul style="list-style-type: none"> • Proc. SDP 11 rev. 06

	<p>- Ispezione sulla produzione/processo</p>	<p>- Pre-spedizione - Carico - Scarico - Post-Spedizione</p>	<ul style="list-style-type: none"> • ISO 2859-1:2007 - Sampling procedure for inspection by attributes - Part 1: Sampling scheme indexed by acceptance quality limit (AQL) for lot-by-lot inspection • US F&DA Investigations Operations Manual - Ed.2021 • EU Directive 2014/32 - Harmonization of the Laws of the Member States relating to the making available on the Market of Measuring Instruments • EU Directive 2014/31 - Harmonization of the Laws of the Member States relating to the making available on the Market of Non-Automatic Weighing Instruments • 97/129/EC: Commission Decision of 28 January 1997 establishing the identification system for packaging materials pursuant to European Parliament and Council Directive 94/62/EC on packaging and packaging waste • ANSI/ASQ Z1.4-2003 (R2018): Sampling Procedures and Tables for Inspection by Attributes • EN 643:2014 Paper and board - European list of standard grades of paper and board for recycling
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			<ul style="list-style-type: none"> • COUNCIL REGULATION (EU) No 333/2011 of 31 March 2011 establishing criteria determining when certain types of scrap metal cease to be waste under Directive 2008/98/EC of the European Parliament and of the Council • Specifiche del Cliente
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Field	Range	Stage	Requirements
<ul style="list-style-type: none"> - Agricultural, food products and their derivatives 	<ul style="list-style-type: none"> - Documental Inspection - Visual Inspection - Production/process Inspection 	<ul style="list-style-type: none"> - Production - Testing - Pre-shipment - Charging - Unloading - Post-shipment 	<ul style="list-style-type: none"> • Proc. SDP 11 rev. 06 • ISO 2859-1:2007 - Sampling procedure for inspection by attributes - Part 1: Sampling scheme indexed by acceptance quality limit (AQL) for lot-by-lot inspection • US F&DA Investigations Operations Manual - Ed.2021 • EU Directive 2014/32 - Harmonization of the Laws of the Member States relating to the making available on the Market of Measuring Instruments • EU Directive 2014/31 - Harmonization of the Laws of the Member States relating to the making available on the Market of Non-Automatic Weighing Instruments • Regulation (EC) No 852/2004 of the European

			<p>Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs</p> <ul style="list-style-type: none"> • Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin • ANSI/ASQ Z1.4-2003 (R2018): Sampling Procedures and Tables for Inspection by Attributes • Client Specification
<p>- Industrial products</p>	<ul style="list-style-type: none"> - Documental Inspection - Visual Inspection - Production/process Inspection 	<ul style="list-style-type: none"> - Production - Testing - Pre-shipment - Charging - Unloading - Post-shipment 	<ul style="list-style-type: none"> • Proc. SDP 11 rev. 06 • ISO 2859-1:2007 - Sampling procedure for inspection by attributes - Part 1: Sampling scheme indexed by acceptance quality limit (AQL) for lot-by-lot inspection • US F&DA Investigations Operations Manual - Ed.2021 • EU Directive 2014/32 - Harmonization of the Laws of the Member States relating to the making available on the Market of Measuring Instruments • EU Directive 2014/31 - Harmonization of the Laws of the Member States relating to the making available on the Market of Non-Automatic Weighing Instruments

			<ul style="list-style-type: none"> • ISO 8015:2011 Geometrical product specifications (GPS) Fundamentals Concepts, principles and rules • ANSI/ASQ Z1.4-2003 (R2018): Sampling Procedures and Tables for Inspection by Attributes • Client Specification
<ul style="list-style-type: none"> - Medicines and cosmetic products 	<ul style="list-style-type: none"> - Documental Inspection - Visual Inspection - Production/process Inspection 	<ul style="list-style-type: none"> - Production - Testing - Pre-shipment - Charging - Unloading - Post-shipment 	<ul style="list-style-type: none"> • Proc. SDP 11 rev. 06 • ISO 2859-1:2007 - Sampling procedure for inspection by attributes - Part 1: Sampling scheme indexed by acceptance quality limit (AQL) for lot-by-lot inspection • US F&DA Investigations Operations Manual - Ed.2021 • EU Directive 2014/32 - Harmonization of the Laws of the Member States relating to the making available on the Market of Measuring Instruments • EU Directive 2014/31 - Harmonization of the Laws of the Member States relating to the making available on the Market of Non-Automatic Weighing Instruments • Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30

			<p>November 2009 on cosmetic products (recast)</p> <ul style="list-style-type: none"> • ISO 15378:2017 Primary packaging materials for medicinal products • ANSI/ASQ Z1.4-2003 (R2018): Sampling Procedures and Tables for Inspection by Attributes • Client Specification
<ul style="list-style-type: none"> - Secondary raw materials and processing waste 	<ul style="list-style-type: none"> - Documental Inspection - Visual Inspection - Production/process Inspection 	<ul style="list-style-type: none"> - Production - Testing - Pre-shipment - Charging - Unloading - Post-shipment 	<ul style="list-style-type: none"> • Proc. SDP 11 rev. 06 • ISO 2859-1:2007 - Sampling procedure for inspection by attributes - Part 1: Sampling scheme indexed by acceptance quality limit (AQL) for lot-by-lot inspection • US F&DA Investigations Operations Manual - Ed.2021 • EU Directive 2014/32 - Harmonization of the Laws of the Member States relating to the making available on the Market of Measuring Instruments • EU Directive 2014/31 - Harmonization of the Laws of the Member States relating to the making available on the Market of Non-Automatic Weighing Instruments • 97/129/EC: Commission Decision of 28 January 1997 establishing the identification system for

		<p>packaging materials pursuant to European Parliament and Council Directive 94/62/EC on packaging and packaging waste</p> <ul style="list-style-type: none"> • ANSI/ASQ Z1.4-2003 (R2018): Sampling Procedures and Tables for Inspection by Attributes • EN 643:2014 Paper and board - European list of standard grades of paper and board for recycling • COUNCIL REGULATION (EU) No 333/2011 of 31 March 2011 establishing criteria determining when certain types of scrap metal cease to be waste under Directive 2008/98/EC of the European Parliament and of the Council • Client Specification
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1. CUSTODIAN

The Quality Manager is the custodian of this procedure.