2020, 3303-ER-01

CERTIFICATION EXPERTS

Expertise Report

Bishop Rotary Tattoo Machines

July 2021

REPORT SPECIFICATION

INVESTIGATION REQUESTED BY

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Report	Expertise Report
Subject	CE Tattoo machines
Reference number	2020, 3303-ER-01
Compiled by	Mr. M.C. de Graaf

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1. INTRODUCTION

Bishop Rotary Tattoo Machines commissioned Certification Experts to guide the CE Marking procedure for their Tattoo machines.

1.1 Scope of the investigation

Bishop Rotary Tattoo Machines requires to CE mark the Tattoo machines, in order to place the equipment on the Union market. Before the Tattoo machines can be placed on the Union market, the conformity with the applicable Directives must be ensured. In order to ensure the conformity, the appropriate procedures for the assessment must have been carried out. The scope of the investigation includes:

- **Classification**
  - Determine the applicable Directive(s) and/or Regulation(s).
  - Selection of the (harmonised) standards.
  - Determine the applicable Conformity Assessment Procedure.
  - Determine your obligations and responsibilities.
- **Technical Documentation**
  - Inventory and evaluation of the available documentation.
  - Assemble the Technical Documentation to be in compliance with all the indicated requirements.
  - Determine the safety status.
- **Finalizing**
  - If applicable, plan of action including advice and recommendations.
  - Declaration of Conformity.

Certification Experts has determined the level of conformity by means of a documentation investigation and by carrying out a test procedure.

2. INVESTIGATED PRODUCT

Before placing the products on the market and/or putting into service, the manufacturer shall ensure that it satisfies the requirements set out in the applicable Directives. The Tattoo machines in table 1 have been taken into account during the investigation.

Table 1. Investigated product

Generic name	Tattoo machine
Models	▼ V6 Rotary Machine:  ▼ Fantom Rotary Machine:  ▼ Microangelo Rotary Machine:  ▼ Bishop Wand (Shader, Packer, Liner): 

2.1 Intended Use

In order to determine the applicable legislation, the intended use requires to be clarified. The intended use of the Tattoo machine is to apply tattoos to the human skin. The Tattoo machine need to be powered by a power supply in order to make the motor move the needle. A controller is used to ensure the proper working of the Tattoo machine.

A power supply and controller are not supplied together with the Tattoo machine. The user must obtain these parts themselves and connect them to the Tattoo machine in order to let the Tattoo machine work as intended.

The needle is also not included with the Tattoo machines. The Tattoo machines will only come into contact with a person when the person takes the Tattoo machine in their hand.

2.2 Limits of Tattoo machine

In this paragraph the limits of the Tattoo machine are stipulated. As mentioned the limit of use, limit of space, limit of time and other limits should be taken into account.

2.2.1 Limit of use

Limit of use	Description
Intended use	
Correct use of the machine	Used to apply tattoos on the human body.
Foreseeable misuse	Any other use.
Operation of the machine	
Operation of the machine	Use by professionals (tattoo artists).
Training of the operator	
User instructions	Will be provided together with the product.
Dangers	Indicated in the instructions.
Interaction with other operators	Not applicable.
Maintenance instructions	Indicated in the instructions.
Safety instructions	Indicated in the instructions.
Operation	
Number of people who are working on the machine	One operator/user.
Number of workstation(s) at the machinery	Not applicable.
Maintenance	
Maintenance	Indicated in the instructions.

Cleaning and frequency of cleaning	
Cleaning products	Indicated in the instructions.
History of accidents	
History of accidents	None known.

2.2.2 Limit of space

Limit of space	Description
Machinery set-up	
Location	Indoor use.
Machinery construction	
Energy supply	External power supply, not delivered with the product.
Space around the machinery	
Other	Handheld product.

2.2.3 Limit of time

Limit of time	Description
Maintenance	
Preventive	This will be outlined in the instructions for use.
Maintenance	This will be outlined in the instructions for use.

3. CLASSIFICATION

In this chapter, Certification Experts has classified the applicable Directive(s) and/or Regulation(s) and their related (harmonized) standards, based on the characteristics, the limits and intended use of the Tattoo machines, see chapter two. Furthermore, Certification Experts indicated the responsibilities and obligations your company has in order to put the Tattoo machines onto the European market.

3.1 European Directives and Regulations

Certification Experts has determined the applicable European Directive(s) and/or Regulation(s) based on the information, characteristics, intended use and limits of the Tattoo machines concerned.

3.1.1 Machinery Directive 2006/42/EC

The Machinery Directive 2006/42/EC is applicable to machinery, interchangeable equipment, safety components, lifting accessories, chains, ropes and webbing, removable mechanical transmission devices and partly completed machinery. The different types of equipment are defined in article 2 of the Machinery Directive. In accordance with article 2 of the Machinery Directive, machinery means:

"an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application. An assembly as referred to in the previous sentence, missing only the components to connect it on site or to sources of energy and motion is also considered to be machinery."

The Tattoo machines are fitted with a drive system other than human or animal effort (implemented motor). The Tattoo machines are only missing the components to connect it to a source of energy, i.e. the power supply and controller. The components of the Tattoo machines are joined together for a specific application, i.e. to apply tattoos onto a human skin. Therefore, the provisions out of the Machinery Directive are applicable to the Tattoo machines.

The Machinery Directive will be considered as the primary Directive. Where the machines are also the subject of other Directives relating to other aspects, the marking shall indicate that the machinery also conforms to the provisions of those other Directives.

3.1.2 Low Voltage Directive 2014/35/EU

The Low Voltage Directive 2014/35/EU shall apply to electrical equipment designed for use with a voltage rating of between 50 and 1 000 V for alternating current and between 75 and 1 500 V for direct current. According to the information provided by the economic operator, the Tattoo machines do not have a voltage rating as they are not supplied with a power supply. Therefore, the Low Voltage Directive is not applicable to the Tattoo machines.

3.1.3 EMC Directive 2014/30/EU

The EMC Directive 2014/30/EU regulates electromagnetic compatibility of equipment and applies to apparatus and fixed installations as defined in Article 3 of the Directive. In accordance with Article 3 of the EMC Directive, apparatus means:

"any finished appliance or combination thereof made available on the market as a single functional unit, intended for the end-user and liable to generate electromagnetic disturbance, or the performance of which is liable to be affected by such disturbance."

The Tattoo machines are apparatus as they are finished appliances, which are liable to generate electromagnetic disturbance and the performance of which are liable to be affected by such electromagnetic disturbance. Therefore, the Tattoo machines fall within the meaning of the EMC Directive.

3.1.4 RoHS Directive 2011/65/EU

The RoHS Directive 2011/65/EU lays down rules on the restriction of the use of hazardous substances in electrical and electronic equipment (EEE) with a view to contributing to the protection of human health and the environment, including the environmentally sound recovery and disposal of waste EEE. In accordance with Article 3 of the RoHS directive, electrical and electronic equipment means:

"Equipment which is dependent on electric currents or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such currents and fields and designed for use with a voltage rating not exceeding 1 000 volts for alternating current and 1 500 volts for direct current."

The Tattoo machines are dependent on electric or electromagnetic fields to work properly and do not exceed the 1000 volt for alternating current and 1500 volt for direct current. The Tattoo machines are therefore qualified as electrical and electronic equipment and fall within the meaning of the RoHS Directive.

3.2 European Harmonised Standards

Directives and Regulations are legal obligations which must be followed. Standards, contrary to the Directives and Regulations, are voluntary consensus-based and as such do not impose any regulations. The European Commission establishes essential safety and health requirements in a Directive/Regulation. European standards (EN) provide the test specifications and test methods.

European Harmonised Standards (official abbreviation: hEN) are used to provide presumption of conformity with the essential requirements of the Directives and Regulations. Based on the applicable Directive(s) and or Regulation(s), the selected standards in table 2 have been used during the investigation.

Table 2. Used standards

Reference	Title of the standard
IEC/EN 55014-1:2017	Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 1: Emission
EN 61000-3-2:2019	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current =16 A per phase)
IEC 61000-4-2:2008	Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test
EN 61000-4-4:2012	Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test
EN 61000-4-5:2014	Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test
EN 61000-4-3:2006	Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test
EN 61000-4-6:2014	Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields
EN 61000-4-11:2004/A1:2017	Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests
IEC/EN 60335-1:2012	Household and similar electrical appliances - Safety - Part 1: General requirements

3.3 Responsibilities and obligations economic operator

Certification Experts has determined the responsibilities and obligations of the economic operator based on the applicable Directives. In accordance with Article 2 of the Machinery Directive, a 'manufacturer' means:

"Any natural or legal person who designs and/or manufactures machinery or partly completed machinery covered by this Directive and is responsible for the conformity of the machinery or the partly completed machinery with this Directive with a view to its being placed on the market, under his own name or trademark or for his own use. In the absence of a manufacturer as defined above, any natural or legal person who places on the market or puts into service machinery or partly completed machinery covered by this Directive shall be considered a manufacturer."

Due to the fact that Bishop Rotary Tattoo Machines designed and manufactured the Tattoo machine and will place the machinery on the Union market, under their own name or trademark, Bishop Rotary Tattoo Machines shall be considered as the manufacturer.

In accordance with the applicable Directives, the manufacturer shall, before placing apparatus on the market, ensure the following:

- Ensure that it satisfies the relevant essential health and safety requirements.
- Ensure that the Technical File is available.
- Provide, in particular, the necessary information, such as instructions.
- Carry out the appropriate procedures for assessing conformity.
- Draw up the EC declaration of Conformity and ensure that it accompanies the machinery.
- Ensure the CE marking is affixed.

4. RISK ASSESSMENT

In this chapter the Risk Assessment will be stipulated. In order to perform a Risk Assessment, the intended use and the limits of the equipment will have to be taken into account in order to determine the applicable hazards. The Risk Assessment has been carried out in accordance with the EN-ISO 12100:2010.

4.1 Risk Assessment Methodology

In order to conduct a Risk Assessment, the following steps should be taken:

1. Determine the intended use of the equipment;

2. Determine the limits of the equipment;
    - *The limits of the equipment include the demarcation within the risk assessment is carried out.*

3. The following step in the Risk Assessment is to identify the hazards. In accordance with annex B.1 of the EN-ISO 12100, the potential hazards of equipment are stipulated. The list is divided in groups of hazards:
    - Mechanical hazards
    - Electrical hazards
    - Thermal hazards
    - Noise hazards
    - Vibration hazards
    - Radiation hazards
    - Material/ substance hazards
    - Ergonomic hazards
    - Hazards associated with the environment in which the machine is used
    - Combination of hazards

4. Determine the life phases of the equipment concerned.

5. Perform the risk estimation.

   By combining the hazardous situations, a worst-case scenario, which could occur, is outlined. This risk is to be estimated and based on the estimation a quantification of the risk shall rise.
   The determined hazards should be converted into risks. The risk estimation is necessary in order to prioritise the risk and to compare the risks. For the estimation of the risks, the following parameters should be taken into account:

   i. *Severity*
      - *The degree of injury*
   ii. *Exposure duration and frequency*
      - *The length of time that a person is exposed and the frequency of occurrence*
   iii. *Probability*
      - *How often is it possible that the 'hazard' occurs*
   iv. *Danger diversion*
      - *Is it possible to avoid the danger as soon as it manifests itself.*

4.2 Risk Assessment

Certification Experts carried out a Risk Assessment on the Tattoo machines. The Risk Assessment, with reference 2020, 3303-RA-v2, has been supplied separately.

5. TECHNICAL DOCUMENTATION

Union harmonisation legislation obliges the manufacturer to draw up Technical Documentation containing information to demonstrate the conformity of the machinery to the applicable requirements. The Technical Documentation has to include a description of the machinery and of its intended use and cover the design, manufacture and operation of the machinery.

The Technical Documentation does not have to be located in the territory of the Community, nor does it have to be permanently available in material form. However, it must be capable of being assembled and made available within a period of time commensurate with its complexity by the person designated in the EC Declaration of Conformity.

5.1 Technical Documentation Checklist

Certification Experts assembled the Technical Documentation based on the composed and provided documentation by Bishop Rotary Tattoo Machines. Furthermore, Certification Experts evaluated the documentation within the Technical Documentation and concluded that the Technical Documentation does not contain all required documentation to determine the compliance with the applicable Directives. The results of the evaluation can be found in the Technical Documentation Checklist, see table 4. The terminology and abbreviations in table 3 are being used in the checklist.

Table 3. terminology and abbreviations

CONFORMITY	
Indication	**Explanation**
Y	The documentation is available.
N	Documentation has not been supplied.
N/A	Not applicable.
ACTION / REMARK	
Indication	**Explanation**
Bold and italic	This documentation must be supplied to determine compliance with the applicable Directives.
Normal	General information or remark, this does not affect the compliance with the applicable Directives.

Table 4. Technical Documentation Checklist

TECHNICAL DOCUMENTATION CHECKLIST			
#	**Requirements**	**Available**	**Remark**
	CONSTRUCTION FILE		
1	A general description of the machinery, e.g. a brochure.	**Y**	
2	The overall design drawing of the machinery.	**Y**	We have cleared this requirement as the products are tested and are found to be safe.
3	Drawings of the control circuits of the machinery.	**Y**	We have cleared this requirement as the products are tested and are found to be safe.
4	Pertinent descriptions and explanations necessary for understanding the operation of the machinery.	**Y**	
5	Full detailed drawings of the machinery.	**Y**	We have cleared this requirement as the products are tested and are found to be safe.
6	Strength calculations of the machinery.	**N/A**	
7	Information regarding sub-assemblies used for the manufacture of the machinery, unless knowledge is not essential for the verification of the conformity of the machinery.	**N/A**	
8	Bill of Material, indicating all sub-assemblies and components.	**Y**	
	RISK ASSESSMENT		
9	The documented Risk Assessment, including the identified hazards.	**Y**	
10	A list of essential health and safety requirements.	**Y**	
11	Description of the protective measures implemented in the machinery.	**Y**	
12	Indication of the residual risks associated with the machinery.	**Y**	
	REPORTS		
13	Technical reports concerning tests carried out by the manufacturer.	**Y**	

TECHNICAL DOCUMENTATION CHECKLIST			
#	**Requirements**	**Available**	**Remark**
14	Standards and technical specifications indicating the covered essential health and safety requirements.	**Y**	
15	The reports on the research and tests on components, fittings or the completed machinery.	**Y**	
INSTRUCTIONS MANUAL			
16	A copy of the instruction's manual of the machine.	**Y**	
17	A copy of the maintenance manual of the machine.	**Y**	
DECLARATIONS AND CERTIFICATES			
18	The EC Declaration of Conformity of the machine.	**Y**	
19	The EC Declaration of Conformity for in the machinery incorporated machinery, where appropriate.	**N/A**	
20	The Declaration of Incorporation for in the machinery incorporated partly completed machinery, where appropriate.	**N/A**	
21	When applicable: Certificates of the notified body which has assessed the machine in accordance with Annex IV of the Machinery Directive.	**N/A**	
SERIES MANUFACTURE			
22	Internal measures to ensure the machinery remains in conformity with the provisions of Machinery Directive, e.g. a certificate of the ISO 9001 quality management system or other proof of quality insurance.	**N**	***The technical documentation does not contain information about the internal measures to ensure quality management. It is strongly advised to add the procedures which are in place to control the quality of the products.***
NOTES			
Note 1: The Technical File must be compiled in one or more official European Community languages.			
Note 2: The Technical File must be kept for at least 10 years following the date of the last unit produced.			

6. ASSESSMENT

A test procedure has been carried out by Certification Experts to determine whether the Tattoo machines comply with the electrical safety and electromagnetic compatibility requirements.

The test procedure has been carried out on 6 March 2020. The Tattoo machines comply with the electrical safety and electromagnetic compatibility requirements. Non-conformities have been detected during the tests. However, these non-conformities originated from the controller and power supply and not with the Tattoo machines themselves.

The test report, with reference 2020, 3303-TR-01, has been supplied to Bishop Rotary Tattoo Machines separately.

Further, to determine compliance with the Machinery Directive, a Risk Assessment has been carried out by Certification Experts, and has been provided separately.

Lastly, Bishop Rotary Tattoo Machines has provided Certification Experts with documentation proving RoHS Compliance of the components of the Tattoo machines. Table 5 indicates the restricted substances and maximum concentration values tolerated by weight in homogenous materials.

Table 5. RoHS Homogeneous Materials

Substance	Maximum concentration percentage
Lead	0,1 %
Mercury	0,1 %
Cadmium	0,01 %
Hexavalent chromium	0,1 %
Polybrominated biphenyls (PBB)	0,1 %
Polybrominated diphenyl ethers (PBDE)	0,1 %
Bis(2-Ethylhexyl) phthalate (DEHP)	0,1 %
Benzyl butyl phthalate (BBP)	0,1 %
Dibutyl phthalate (DBP)	0,1 %
Diisobutyl phthalate (DIBP)	0,1 %

Based upon the carried-out assessment, Certification Experts determined that the RoHS requirements have been met.

Certification Experts is strongly advising to add the procedures for quality control to the technical documentation. Other than the aforementioned, the Tattoo machines comply with the applicable legislation.

6.1 Marking of Machinery

In accordance with the applicable legislation is determined which particulars are required for the marking of the Tattoo machines. The following particulars are required for the Tattoo machines. It is strongly recommended to add this information to the Tattoo machines.

- the business name and full address of the manufacturer,
- designation of the machinery,
- the CE Marking (see Annex I),
- designation of series or type,
- type, batch or serial number,
- the voltage on which the equipment operates,
- the year of construction, that is the year in which the manufacturing process is completed.

7. CONCLUSION

Bishop Rotary Tattoo Machines commissioned Certification Experts to carry out guidance with the CE marking procedure for their Tattoo machines Fantom Rotary, Microangelo Rotary, V6 Rotary and Bishop Wand.

Based on the classification, Certification Experts determined that the Tattoo machines fall within the scope of the following Directives:

- Machinery Directive 2006/42/EC
- EMC Directive 2014/30/EU
- RoHS Directive 2011/65/EU

Certification Experts carried out a test procedure to determine whether the Tattoo machines comply with the electrical safety and electromagnetic compatibility requirements. In accordance with the results of the aforementioned test procedure, the Tattoo machines comply with the electrical safety and electromagnetic compatibility requirements. The test report, with reference 2020, 3303-TR-01, has been supplied to Bishop Rotary Tattoo Machines separately.

Further, a documentation investigation has been carried out to determine whether the Tattoo machines comply with the Machinery Directive and the RoHS Directive. Based on the provided documentation and the carried out Risk Assessment, compliance with the aforementioned directives have been assured.

Bishop Rotary Tattoo Machines compiled the Technical File for the Tattoo machines. Certification Experts determined that the provided documentation satisfy the applicable documentation requirements. Certification Experts does strongly advise to add the procedures for quality control to the technical documentation.

The economic operator shall affix the CE marking to prove conformity with the provisions of the applicable Directives, see Annex I. Finally, the Declaration of Conformity, see Annex II, will need to be supplied with every product.

Breukelen, July 2021

CERTIFICATION EXPERTS B.V.

ANNEX I CE MARKING

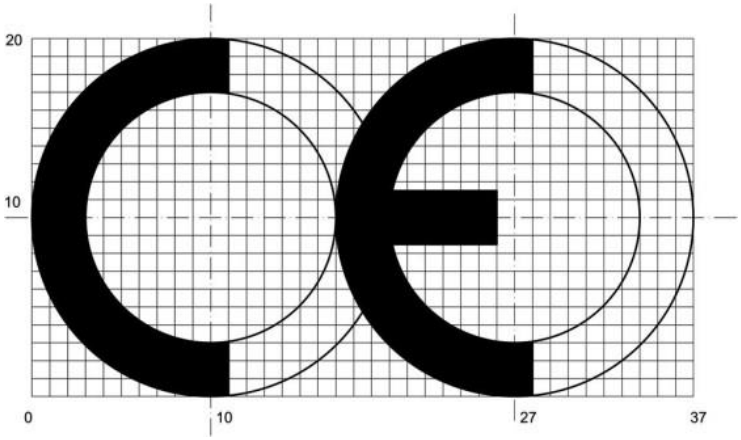
The CE marking must be affixed visibly, legibly and indelibly to the machinery or to its data plate. However, where this is not possible or not warranted on account of the nature of the machinery, it must be affixed to the packaging, if any, and/or to the accompanying documents.

The requirement for visibility means that the CE marking must be easily accessible for all parties. It could, for instance, be affixed on the back or underside of the machinery. A minimum height of 5 mm is required to ensure that it is legible. However, the minimum dimension of the CE marking may be waived for small devices or components. The CE marking must remain visible, legible and respects its proportions. It must also be indelible so that it cannot be removed under normal circumstances without leaving noticeable traces. Nevertheless, this does not mean that the CE marking must form an integral part of the machinery. However, in certain cases affixing of the CE marking to the machinery is impossible or not possible under reasonable technical or economic conditions.

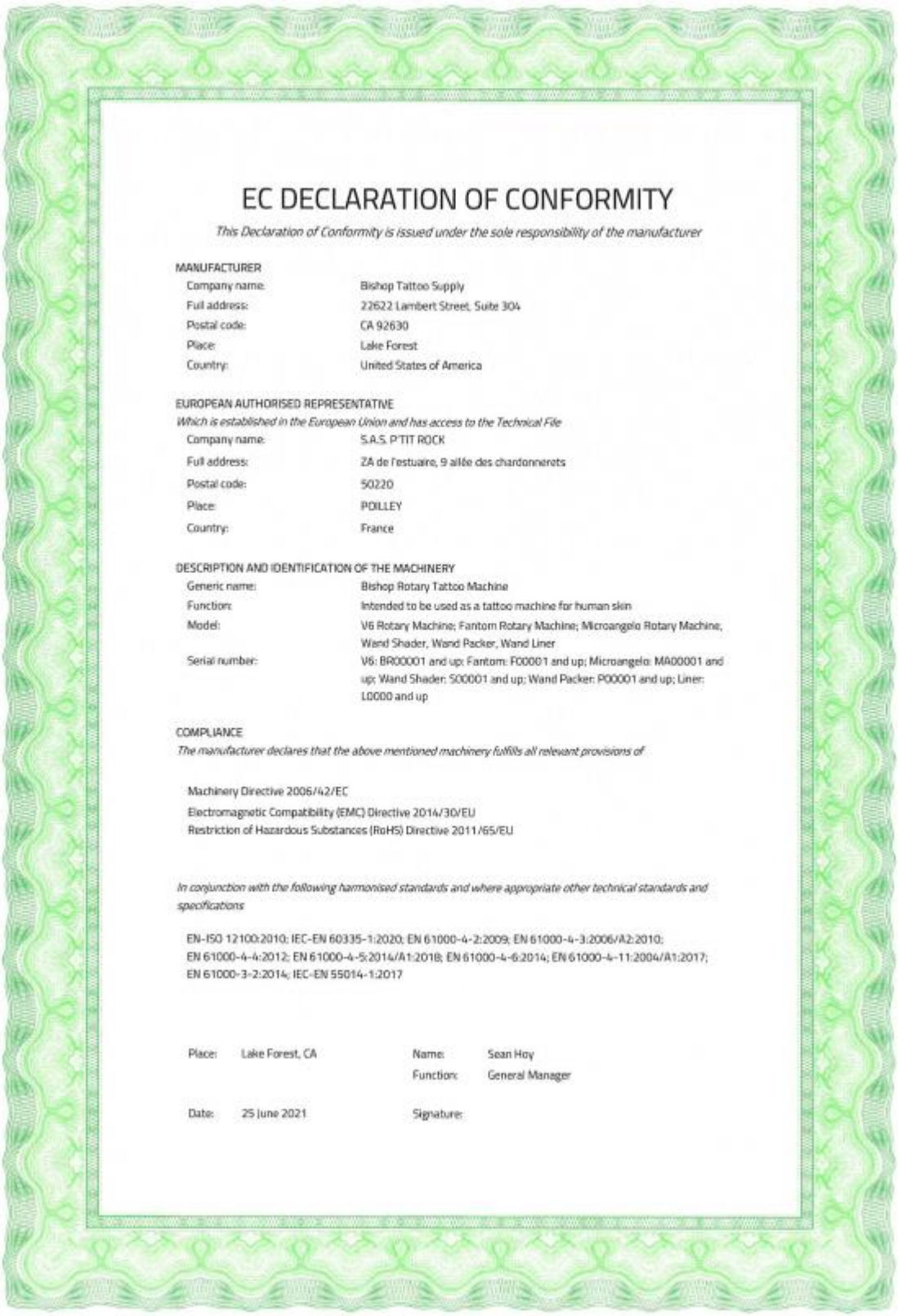
Furthermore, there can be cases where the minimum dimensions for the affixing cannot be respected or cannot be ensured that the CE marking is visibly, legibly and indelibly affixed. In such cases, the CE marking can be affixed to the packaging, if it exists, and/or to the accompanying document, where the Union harmonisation legislation concerned provides for such documents. The CE marking on the machinery may neither be omitted nor be moved to the packaging or accompanying documents on purely aesthetic grounds.

Regulation (EC) 765/2008 and Decision 768/2008/EC lay down that the CE marking must have the dimensions, format and proportions defined in Annex II of Regulation (EC) No 765/2008 and be legible and clearly affixed. Regulation (EC) 765/2008 and Decision No 768/2008/EC do not forbid any kind of design (e.g. “hollow” design) as long as the above conditions are respected. Electronic labelling, however, is not allowed.

The CE marking shall consist of the initials ‘CE’ taking the following form:



ANNEX II EC DECLARATION OF CONFORMITY



EC DECLARATION OF CONFORMITY

This Declaration of Conformity is issued under the sole responsibility of the manufacturer

MANUFACTURER

Company name:	Bishop Tattoo Supply
Full address:	22622 Lambert Street, Suite 304
Postal code:	CA 92630
Place:	Lake Forest
Country:	United States of America

EUROPEAN AUTHORISED REPRESENTATIVE

Which is established in the European Union and has access to the Technical File

Company name:	S.A.S. P'TIT ROCK
Full address:	ZA de l'estuaire, 9 allée des chardonnerets
Postal code:	50220
Place:	POILLEY
Country:	France

DESCRIPTION AND IDENTIFICATION OF THE MACHINERY

Generic name:	Bishop Rotary Tattoo Machine
Function:	Intended to be used as a tattoo machine for human skin
Model:	V6 Rotary Machine; Fantom Rotary Machine; Microangelo Rotary Machine, Wand Shader, Wand Packer, Wand Liner
Serial number:	V6: BR00001 and up; Fantom: F00001 and up; Microangelo: MA00001 and up; Wand Shader: S00001 and up; Wand Packer: P00001 and up; Liner: L0000 and up

COMPLIANCE

The manufacturer declares that the above mentioned machinery fulfills all relevant provisions of

Machinery Directive 2006/42/EC
Electromagnetic Compatibility (EMC) Directive 2014/30/EU
Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU

In conjunction with the following harmonised standards and where appropriate other technical standards and specifications

EN-ISO 12100:2010; IEC-EN 60335-1:2020; EN 61000-4-2:2009; EN 61000-4-3:2006/A2:2010; EN 61000-4-4:2012; EN 61000-4-5:2014/A1:2018; EN 61000-4-6:2014; EN 61000-4-11:2004/A1:2017; EN 61000-3-2:2014; IEC-EN 55014-1:2017

Place:	Lake Forest, CA	Name:	Sean Hoy
		Function:	General Manager
Date:	25 June 2021	Signature:	

CERTIFICATION
experts