DECLARATION OF COMPLIANCE

This document is a Document of Compliance within the meaning of Article 16(1) of Regulation (EC) No. 1935/2004 on materials and articles intended to come in contact with food.

1 General Product Information

a) Name(s) of product(s) SteriBag Premium 5344-8000

b) Description of product(s) Sterile Sampling Bag

c) Date 23 March 2016

2 Compliance with General Food Contact Legislation

The products named on this declaration comply with the applicable requirements of EU "Framework" Regulation (EC) No. 1935/2004 on materials and articles intended to come into contact with food and with Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.

The manufacture of the product(s), it follows the good manufacturing practice requirements according to FPE's "Code for Good Manufacturing Practices for Flexible and Fibre-based Packaging for Food".

3 Conditions of Use

This declaration is valid for the following conditions of use: packing and storing of ambient and chilled items including: food, pharmaceutical and biological samples

Note that, *if the final consumer subjects the filled pack to increased temperatures, e.g. through microwaving or "boil-in-the-bag", the packer must ensure that suitable instructions are given to the consumer so that the above conditions of use are not exceeded.*
This validity only applies to migration and legislative compliance and not to technical fit-for use.

As specified in Article 17.2 (c) of the Plastics Regulation, a surface to volume ratio of 6 dm^2/kg food has been used to determine compliance.

4 Plastics Regulation

a) The products named on this declaration comply with the applicable requirements of EU Plastics Regulation No. 10/2011 and its amendment as follows:

i) The plastics are manufactured only with monomers, other starting substances and additives that are authorised under the Plastics Regulation.

ii) Our suppliers have informed us that any substances intentionally added to the plastics, not subject to listing in Annex I, comply with the relevant requirements of the Framework Regulation and a risk assessment in accordance with Article 19 of the Plastics Regulation has been performed.

iii) A risk assessment in accordance with Article 19 of the Plastics Regulation has been performed on *these or similar* products and the assessed reaction intermediates, decomposition or reaction products in the requirements of the Framework regulation.

iv) The product(s) comply with the Overall Migration Limit (OML) following evaluation of relevant samples under the following conditions:

Bürkle GmbH
Rheinauen 5 | D-79415 Bad Bellingen
Phone +49 (0) 76 35 8 27 95-0 | Fax +49 (0) 76 35 8 27 95-31
info@buerkle.de | www.buerkle.de

Sitz Bad Bellingen, Registergericht:
Amtsgericht Freiburg i. Br. | HRB 701113
VAT-No. DE 263 386 955 | DIN EN ISO 9001
Geschäftsführer Martin Saint-Denis

Martin Schweizer
Quality Manager
qm@buerkle.de

10 days @ 40ºC in simulant B, D1 & D2

Note that the rules for verifying OML (for plastic materials) are laid down in Regulation (EU) No. 10/2011 (as amended to date). During a transition period from 01/01/2013 until 31/12/2015 the test conditions of Directive 82/711/EEC as well as the simulants of Directive 85/572/EC as amended remain valid in parallel with Annex V of Regulation 10/2011. Detailed methods have been published in the EN 1186 series of standards by CEN.

b) Substances with restrictions. The products **may** contain some or all of the following substances which are listed in Annexes I and II of the Plastics Regulation with restrictions:

FCM No.	Ref. No.	CAS No.	Substance Name	SML (mg/kg)	Compliance Method*
356	18820	0000592-41-6	1-hexene	3	4
264	22660	0000111-66-0	1-octene	15	4
132	26140	0000075-38-7	vinylidene fluoride	5	4
282	18430	0000116-15-4	hexafluoropropylene	ND	4
433	68320	0002082-79-3	octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	6	4
402	96240	0001314-13-2	zinc oxide	25 expressed as zinc	4
106	24550 / 89040	0000057-11-4	stearic acid	25 (expressed as zinc)	4
69	74400	26523-78-4	phosphorous acid, tris(nonyl-and/or dinonylphenyl) ester	30	4
384	40000	0000991-84-4	2,4-bis(octylmercapto)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine	30	4
758	38940	0110675-26-8	2,4-bis(dodecylthiomethyl)-6-methylphenol	5	4
223	13630	0000106-99-0	butadiene	1 in plastics or ND in the food	4
209	17050	0000104-76-7	2-ethyl-1-hexanol	30	4

Restrictions can be a specific migration limit (SML), a maximum concentration (QM) in the plastic or a "no detectable migration" (ND) requirement at a certain detection limit (DL). Suffix (T) indicates a combined restriction for 2 or more substances.

*Compliance methods:

1 Compliance statements from the suppliers of the relevant components
2 Worst case calculation based on information from the suppliers of the relevant components
3 Migration modelling
4 The results of overall migration testing
5 The results of specific migration testing
6 Determination of PAA in laminate according to §64 LFGB L.00.00-6 following extractable of migratable isocyanates and conversion into amines.
7 Other user defined methods

c) Dual use additives.
As required by Regulation (EU) No. 10/2011 the following table identifies substances used as additives in plastics and subject to a restriction in food through an authorisation as a food additive or a flavouring which may be present in the product(s).

In absence of a Community reference list of these substances, or a marking in regulation (EU) No. 10/2011, the following information received from our suppliers can only be considered preliminary:

PM/ref	Food Additive	CAS Number	Component	Restriction in plastics	Product listed above complies with this restriction (YES/NO)
42500	E170	471-34-1	Calcium carbonate	n/a	Yes
64720	E530	1309-48-4	Magnesium oxide	n/a	Yes
79040	E432	9005-64-5	Polyethylene glycol sorbitan monolaurate	n/a	Yes
86240	E551	7631-86-9	Silicon dioxide	n/a	Yes
92080	E553b	14807-96-6	Talc	n/a	Yes
14680 / 44160	E330	77-92-9	Citric acid	n/a	Yes
24550 / 89040	E570 / E572	57-11-4	Stearic acid / calcium stearate	25 expressed as zinc	Yes
76960 / 23590	E1521	25322-68-3	Polyethylene glycol	n/a	Yes

5 Additional Information on Plastic Layers

The plastic complies with the following:

- BfR Recommendation III for PE
- FDA 21 CFR 177, parts 170-179 for good manufacturing practices
- FDA 21 CFR 177.1520 Olefin Polymers

6 Recycled Plastic Materials

These products do not contain recycled plastic materials as defined by and subject to Regulation (EC) No. 282/2008.

7 Printing Inks

Where present, based on information received from suppliers, the inks used to manufacture the product(s) are in compliance with the EuPIA exclusion list and are formulated and manufactured in accordance with the EuPIA "Guideline on Printing Inks applied to the non-food contact surface of food packaging".

Substances that are not listed in the Plastics Regulation comply with Article 3 of Regulation (EC) No. 1935/2004.

All starting substances of inks are listed in the Swiss Ordinance on Materials and Articles in Contact with Food, section 8b, Packaging Inks, Art. 26e - 26i, Annex 6.

The products comply with Section A of the Annex of Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.

8 Adhesives

The components are in compliance with the Commission Regulation (EU) 10/2011 on plastic materials and articles intended to come into contact with food, except the aliphatic hydrocarbon resin, which is currently not listed in the Unionlist, however in compliance with the “Warenwet”, Paragraph 10: Coatings.

Substances in the adhesive that are not listed in any of the above comply with Article 3 of Regulation (EC) No. 1935/2004, final check of suitability regarding 1935/2004 remains with the user.

All components are listed in FDA (food drug administration) regulation, in 21CFR §175.105 (adhesives for use as component of articles in packaging, transport or holding food). This regulation specifies that the adhesive is either separated from food by a functional barrier, or used subject to the following additional limitations: (a) The amount of adhesive that contacts packaged dry foods shall not exceed the amounts of good manufacturing practice; (b)The quantity of adhesive that contacts packaged fatty and aqueous foods shall not exceed the trace amount at seams and at edge exposure between packaging laminates that may occur within the limits of good manufacturing practice, and under normal conditions of use the packaging seams or laminates will remain firmly bonded without visible separation.

Some components are in compliance with Decree Nr. 2007-766 of May, 10th. 2007 and its amendments.
Some components are listed in BfR XXV- Hard Paraffins, Microcrystalline Waxes and Mixtures of these with Waxes, Resins and Plastics, valid for the application with non-fatty food only.

Other components comply with BfR XXI. Commodities based on Natural and Synthetic Rubber.

This food contact status is based on the compositional information provided by the supplier who may rely upon information provided by their raw material supplier and is given on the best of our knowledge. The technical suitability for the final application needs to be determined by the user under the intended conditions of use. This might cover extraction and/or migration tests and the evaluation of the possible influence on the organoleptic properties of the food. Should you require any further information please contact us.

9 Epoxy Derivatives

The products do not contain epoxy derivatives.

10 Release Liner

The supplier of the has confirmed that the MPT film (foil liner) used to manufacture the above mentioned products complies with:-

- EC 2023/2006
- Regulation (EC) 1935/2004
- FDA 21 CFR §177.1630
- BFR XVII

The product manufacturer also confirms that the silicone coating used to manufacture the above mentioned product complies with the following:-

- Regulation (EC)1935/2004
- LFBG §§30 and 31

11 Active and Intelligent Packaging

These products do not contain active and intelligent materials or articles as defined by and subject to Regulation (EC) No. 450/2009.

12 Heavy Metals

The products are in compliance with the limit of 100 ppm laid down by Directive 94/62/EC and in the Model Toxics in Packaging Legislation (as drafted by the Toxics and Packaging Clearinghouse / Source Reduction Council of CONEG) for the sum of concentration levels of lead, cadmium, mercury and hexavalent chromium.

13 Other Statements

Our suppliers have not informed us that they have intentionally added to the plastics any substances which are not subject to listing in Annex I.

These product(s) do not intentionally contain in the composition any of the chemicals regulated in the following documents. The presence of these substances is then not foreseeable in the final product. However, specific analysis to assure the absence of most of these chemicals has not been performed:

- GMO (Genetically Modified Organisms) - according to the information from our raw materials suppliers, this product does not contain intentionally in its composition any GMO
- Nanoparticles - The supplier does not incorporate in this product any additive in nanoparticle form
- California Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986) - this product does not intentionally contain any of the chemicals regulated in quantities above the applicable limits
- Conflict Minerals (US Dodd-Frank Wall Street and Consumer Protection Act 2010) - the product does not intentionally contain in its composition any of the metals Tantalum, Tin, Gold and Tungsten.

This product may contain additives of animal origin, but according to the information from our suppliers, the processing and transformation conditions are more severe than those included in the Commission Decision 2001/2, Directives 2000/6, and 2001/83, Regulations 999/2011, 1326/2001 and 1069/2009 and Guidance EMA/410/01 rev.3 (2011), so there is no risk of transmitting BSE/TSE.

14 Absence of Substances

Our supplier does not intentionally incorporate in the composition of this product any of the following chemicals. Although their presence in the final product is not foreseeable, specific analyses to assure the absence of these chemicals have not been performed. This is a non- exhaustive list of substances:

- Arsenic and arsenic compounds
- Asbestos
- Biocides
- Bisphenol A (BPA), Bisphenol F (BPF) and Bisphenol S (BPS)
- Formaldehyde
- Halogens and halogenated compounds
- Natural rubber latex
- Phthalates
- PVC
- Toluene
- VOC's

15 Sterility

Where the product is supplied as sterile, sterility is claimed subject to the results of sterility tests, the use of 25 kGy to achieve an SAL of at least 10-6 is justified
The justification of the use of 25 kGy of radiation as a sterilizing dose is based on the microbiological quality of the product. Our report (VDMax25) provides details of the work undertaken to demonstrate that the routine use of 25 kGy is adequate to provide product detailed above with a Sterility Assurance Level of at least 10-6.
Bioburden evaluation was used to determine a sub-process verification dose of radiation. Product was irradiated at this verification dose and subjected to sterility testing.
Following the outcome of the sterility testing:
The use of 25kGy as a routine sterilization dose is substantiated.

References:
BS EN ISO 11137-1 :2006, Sterilization of healthcare products -
Radiation - Part I: Requirements for development, validation and routine control of a sterilization process for medical devices.

BS EN ISO 11137-2:2012, Sterilization of healthcare products -
Radiation - Part 2: Establishing the sterilization dose.

16 REACH

We are fully aware of REACH and the timetable for pre-registration of substances. The first point at which information may be available from our suppliers is after the December 2010 deadline, this will be a sliding scale process through to June 2018 and during the whole of this period we can expect to receive information.

However, as a downstream user of chemicals we must wait until the phased registration process is complete before we can enter into meaningful discussions with our suppliers. At this stage there is no indication that the registration process will affect any of our raw material supply.
Obviously at this stage it is not possible to predict the exact situation with regard to the products used in our manufacturing process, however we will be working with our suppliers on the 'Exposure Scenarios' which will provide all the necessary information.

17 Disclaimer

This Declaration of Compliance describes the status of the products specified under General Product Information. The user of the product (or downstream user, if applicable) is responsible for ensuring that the finished packaging complies with applicable migration limits in the packed product itself under actual conditions of use. Furthermore, for packaging used with food the food packer is responsible for verifying possible interactions of the product(s) or its components with the foodstuffs (e.g. modification of odour, taste, consistency, migration etc) which are to be checked prior to use and in function of the end uses.

The declaration is based on our current state of knowledge and information provided by our supplier at the time that the document was drawn up. The supplier – Bürkle GmbH in Bad Bellingen/Germany – is certified according to the standard DIN EN ISO 9001 by the DQS (German Society for Quality Assurance) since 1995. The number of certificate is 2284-08.

23. March 2016

Bürkle GmbH, Bad Bellingen,
Martin Saint-Denis, Managing Director