

## DECLARATION OF CONFORMITY UE



COMPANY	BICARjet S.r.l.
COMPANY ADDRESS	Via Nona Strada, 4 - 35129 Padova, Italia
REGISTRATION NUMBER (SRN)	Requested, awaiting release

### DECLARES UNDER ITS OWN AND ONLY RESPONSIBILITY THAT THE DEVICE

COMMERCIAL NAME	SAFE CleanBox
MODEL	<ul style="list-style-type: none"><li>○ <b>STK 103</b></li><li>○ <b>STK 113</b></li><li>○ _____</li></ul>
SERIAL NUMBER	
UDI-DI basic	<b>805159748SAFECLEANBOX2K</b>
CND CODE	V0799 - PRODUCTS FOR CLEANING MEDICAL DEVICES NOT INCLUDED IN OTHER CLASSES
INTENDED USE	Preventive and preparatory surface preparation for the reconditioning process of D.M.R. The process is carried out by using a jet of compressed air and bicarbonate with or without water with the effect of removing any contaminant from the surface, allowing to enhance the result of the subsequent stages. This operation is conceptually similar to the manual brushing operation of the DMR, normally performed before they are subjected to subsequent washing, disinfection and / or sterilization processes.
DESCRIPTION	System consisting of a "glove box" type cabin in which it is possible to clean reusable medical devices (DMR), before they are subjected to subsequent washing and sterilization processes. Cleaning takes place by dispensing a jet of bicarbonate, water and compressed air: this process is similar to mechanical brushing with high efficacy and efficiency.

### COMPLIES WITH THE REGULATION (UE) 2017/745

CLASSIFICATION	Class I (Annex VIII rule 13)
CONFORMITY ASSESSMENT PROCEDURE	Annex II and III

### AND TO THE FOLLOWING LEGISLATIVE ACTS WHICH PROVIDE FOR THE RELEASE OF AN EU DECLARATION OF CONFORMITY:

**Direttiva 2012/19/EU on waste electrical and electronic equipment (WEEE/RAEE)**

**Direttiva RoHS 2011/65/EU (ANNEX I)**

**Declaration of Conformity issue date**

Padova, 24/11/2021  
LEGAL REPRESENTATIVE  
Signature  
M. Paolo Alessandro Sommacal

## ANNEX I

### Declaration of Conformity to EU RoHS

Products are in compliance with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (also known as "RoHS Recast"). In addition, this declaration of conformity is issued under the sole responsibility of the manufacturer, specifically, products manufactured do not contain the substances listed in the table below in concentrations greater than the listed maximum value.

This declaration also implements the COMMISSION DELEGATED DIRECTIVE (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU.

Substance	Maximum Limit %
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
Butyl benzyl phthalate (BBP)	0,1
Dibutyl phthalate (DBP)	0,1
Diisobutyl phthalate (DIBP)	0,1