**Please complete all applicable questions on this form and return to EuroCaps. Thank you for your co-operation**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **1** | **Manufacturer Details** | | | | |
|  | **Manufacturer: Name:** | RED B.V. | | | |
|  | **Address:** | Einsteinstraat 37 | | | |
|  |  | 3316 GG Dordrecht | | | |
|  |  | The Netherlands | | | |
|  |  | | | | |
|  | **Contact Name:** | Mrs. Patricia Hoff Quirino | | | |
|  | **Position:** | Sales Manager | | | |
|  |  | | | | |
|  | **Telephone:** | +31 85 049 15 00 | | | |
|  | **E-mail:** | info@redlecithin.com / phoff@redlecithin.com | | | |
|  | **Website:** | www.redlecithin.com | | | |
|  | | | | | |
| **2** | **General Questions** | | | | |
|  | Who is responsible for Quality? | | Name: | Mr. Antopine van den Broek | |
|  | Job Title: | | | Quality Manager | |
|  |  | | | | |
|  | Total number of employees in production: | | | 3 | |
|  |  | | | | |
|  | Total number of employees in QA/QC: | | | 3 | |
|  |  | | | | |
|  | Total number of employees: | | | 15 | |
|  |  | | | | |
|  | Would it be possible for Eurocaps to carry out a quality audit of your company? | | | |  |

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| **3** | **Manufacturing Questions** | | | | |
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|  | **Quality Assurance** | | | | |
|  | Does your company operate a recognised quality management system? | | | |  |
|  | *If yes, please specify:* | | | | FSSC 22000, GMP+ B1, Kosher, Halal, SKAL (Organic), Non-GMO IP |
|  |  | | | | |
|  | Does your company carry out self-audits? | | | |  |
|  |  | | | | |
|  | Is a representative sample of the product tested following manufacture? | | | |  |
|  |  | | | | |
|  | Who is responsible for the final release of the product? | | Name: | Mr. Rob Blokvoord | |
|  | Job Title: | | | Director | |
|  |  | | | | |
|  | **Premises** | | | | |
|  | Is the product manufactured at a ‘single-active’ site? i.e. is there only on material produced on site? | | | |  |
|  |  | | | | |
|  | Are you a registered food producer? |  | | | |
|  |  | | | | |
|  | Is the manufacturing/packing site subject to inspection by any regulatory authority (e.g. MHRA, FDA) or certified to a recognised standard (e.g. BRC, ISO)? | | | |  |
|  | *If yes, please specify:* | | | | inspected by Dutch Food and Feed Authority "NVWA". Certified and audited by FSSC 22000, GMP+ B1, Kosher, Halal, SKAL (Organic), Non-GMO IP. Registered at FDA |
|  |  | | | | |
|  | Please give details of the age, size and type of construction of the premises: | | | | 700m2 lot; built in 1990; concrete/metal production hall, office available, food dedicated production rooms |
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|  |  | | | | |
|  | Are changing areas provided for production staff? | | | |  |
|  |  | | | | |
|  | Are handwash and toilet facilities provided for production staff? | | | |  |
|  |  | | | | |
|  | Are smoking, eating, or drinking prohibited in the production area? | | | |  |
|  |  | | | | |
|  | Is the production area segregated from other areas? | | | |  |
|  |  | | | | |
|  | Are the walls, floors, and ceilings in the production area smooth, non-porous and easily cleaned? | | | |  |
|  |  | | | | |
|  | Are there pest control measures on site? | | | |  |
|  | *If yes, please specify:* | | | | Executed by Rentokil |
|  |  | | | | |
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|  |  | | | | |
|  | Is a maintenance contract held with a pest control company? | | | |  |
|  |  | | | | |
|  | **Manufacturing/packing procedure** | | | | |
|  | Is a retained sample kept for each batch? | | | |  |
|  |  | | | | |
|  |  | | | | |
|  | Are there cleaning procedures and schedules in place for the manufacturing areas? | | | |  |
|  |  | | | | |
|  | **Please attach a summary of the manufacturing process (including the procedure for packing and labelling) and your HACCP plan(s)** | | | | |
|  |  | | | | |
|  | Are materials manufactured to a formal specification? | | | |  |
|  |  | | | | |
|  | Is a certificate of analysis provided with each batch? | | | |  |
|  |  | | | | |
|  | Are products manufactured in accordance with a written manufacturing method? | | | |  |
|  |  | | | | |
|  | Are the manufacturing attributes recorded on a batch manufacturing record? | | | |  |
|  |  | | | | |
|  | Does the manufacturing record permit full lot traceability? | | | |  |
|  |  | | | | |
|  | For how long are manufacturing records retained? | | | | minimum 5 years |
|  |  | | | | |
|  | **Training and Hygiene** | | | | |
|  | Are staff trained to permit them to adequately carry out their job functions? | | | |  |
|  |  | | | | |
|  | Does training for production staff include hygiene training? | | | |  |
|  |  | | | | |
|  | Are production staff required to wear protective clothing? | | | |  |
|  | *If yes, please specify:* | | | | must wear in production rooms |
|  |  | | | | |
|  |  | | | | |
|  |  | | | | |
|  | Is there a jewellery policy? | | | |  |
|  | *If yes, please specify:* | | | | no jewelry allowed in production rooms |
|  |  | | | | |
|  |  | | | | |
|  |  | | | | |
|  | Are new employees subject to a pre-employment medical check? | | | |  |
|  | **Contamination** | | | | |
|  |  | | | | |
|  | Is there a glass control procedure? | | | |  |
|  |  | | | | |
|  | Please give details of your allergen control procedures: | | | | see statement 14 attached |
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|  | **BSE/TSE Information** | | | | |
|  | *Before completing this section it is highly recommended that you familiarise yourself with the content of European Pharmacopeia general chapter 5.2.8 (Minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products).* | | | | |
|  | Are any materials of animal origin stored or processed on site? | | | |  |
|  | *If yes, please give full details listing the animal species:* | | | |  |
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|  | *Cattle, sheep, goats and animals that are naturally susceptible to infection with transmissible spongiform encephalopathy agents or susceptible to infection through the oral route other than humans and non-human primates are defined as ‘TSE-relevant animal species’.*  *Regulatory guidance and position papers have been issued by the Committee for Medicinal Products for Human Use and its Biologics Working Party on human tissue derived medicinal products in relation to CJD and vCJD. Such guidance can be found on http://www.ema.europa.eu.*  *Note: Pigs and birds are not naturally susceptible to infection via the oral route, therefore they are not TSE-relevant animal species. Dogs, rabbits and fish are non TSE-relevant animal species.* | | | | |
|  |  | | | | |
|  | Are any materials from TSE-relevant animal species stored or processed on site? | | | |  |
|  |  | | | | |
|  | *If* ***yes****, copies of the certificate(s) of suitability to the monographs of the European Pharmacopoeia (CEPs) MUST be submitted with this application. Should any new material of animal origin from TSE-relevant species be introduced into your facility then you MUST notify EuroCaps Limited* | | | | |
|  |  | | | | |
|  | *If* ***no****, you MUST notify EuroCaps Limited immediately if you introduce animal material from TSE-relevant species into your facility* | | | | |
|  |  | | | | |
|  | **I have read, understood, and accept the above conditions** | | | | |
|  |  | | | | |
|  | Name: R.A.G. Blokvoord | | | | Date: 24-8-2023 |

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| **4** | **Ethical Trading Questions** | |
|  | *In the manufacture and supply of this product Eurocaps Ltd encourages all its supply partners to work with us to ensure our supply chain benefits all those workers operating within it no matter their race, age, sex, religion, mental or physical ability and/or any other social position. Whilst these questions are directed to you, we expect that you will filter these requirements back through your own supply chains to ensure compliance with all social, economic and welfare regulations in place throughout the world, thus ensuring that we make a contribution to everyone’s lives in as positive a way as possible.* | |
|  |  | |
|  | Are workers freely, and without discrimination allowed membership of a Trade Union and/or company committee scheme? |  |
|  |  | |
|  | What is the minimum age of employment and what measures are in place to ensure that no child labour is used anywhere within the supply? | 18 years; we comply with Dutch law |
|  |  | |
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|  |  | |
|  | Are workers paid a fair wage, in line with local government legislation? |  |
|  |  | |
|  | Are workers encouraged to work no more than a maximum number of hours per week, in line with local government legislation? |  |
|  |  | |
|  | Are measures taken to ensure all employees are treated fairly irrespective of age, race, sex and physical and mental capabilities? |  |
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|  | Are you registered to SEDEX, The Ethical Trade Initiative Base Code or a similar organisation? |  |
|  | *If yes, what is your registration number?* |  |

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| **5** | **Declaration** | |
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|  | **The information provided on this form is correct to the best of my knowledge and**  **I agree to inform EuroCaps Limited of any changes in the information provided** | |
|  |  | |
|  | Signed: R.A.G. Blokvoord | Date:     24-8-2023 |
|  |  | |
|  | Position: Director | |