**ENGLISH VERSION**

|  |  |
| --- | --- |
| Instructions for the customer: | Please fill out the form and contact us if you have any questions or concerns. Please send the completed form as a **Word file** to Emergency@1scUSA.com *Please number your attachments / evidences and label the files clearly.* |

|  |  |  |  |
| --- | --- | --- | --- |
| Name of the company: |  | COID: |  |
| Reported by: |  | Date of reporting: | \_\_ . \_\_ . 202\_ |
| Address of certified site |  |
| Name of contact person in certified site: |  |
| Position |  |
| Email |  |
| Telephone |  |

|  |  |
| --- | --- |
| Please describe the situation / issue in a few words |  |
| Please classify the notification (the use of more than one tick box might be necessary) | **Product related:**[ ]  Decree/penalty/measure on the part of the authorityplease describe: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  Recall (Product Safety)[ ]  Withdrawal (Product Safety)[ ]  Products removed from sale due to other reasons: please describe: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  Other actions for affected goods:please describe: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Company related:**[ ]  Decree/penalty/measure on the part of the authorityplease describe: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  Change of key person[ ]  Change of address[ ]  changes in operation process(es) [e.g.: facilities, technologies, building structures, etc.].please describe: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  other: (force majeure such as fire or natural disasters / blackmail / media problems / hacker attack / etc.)Please describe: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| List the immediate actions taken, if any: |  |

**To be completed in the event of a recall, withdrawal, authority/official measures or other product-related action:**

|  |  |
| --- | --- |
| Date for product-related action: | \_\_ . \_\_ . 202\_\_ |
| Affected products: |  |
| Date of manufacture: | \_\_ . \_\_ . 202\_\_ |
| Lot number(s):  |  |
| Quantity produced: |  |
| Quantity still in stock: |  |
| Quantity delivered: |  |
| Territories/areas to which the product was (also) shipped:  |  |
| Summary of effectiveness of product related actions. |  |

|  |  |
| --- | --- |
| Reason for product-related action: |  |
| Is the product classified as (the use of more than one tick box might be necessary) | [ ]  not legal[ ]  not marketable[ ]  unsafe[ ]  immediate health risk[ ]  quality defect[ ]  fraud[ ]  other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date of the decision: \_\_ . \_\_ . 202\_\_ |
| Is it necessary to inform the supervisory authority? | [ ]  YES[ ]  NOPlease explain the decision:  |
| Name of supervisory authority informedDate / Way of information: | \_\_ . \_\_ . 202\_\_ / [ ]  E-Mail, Online form, Fax [ ]  Telephone |
| Have any illnesses or injuries been reported in connection with this notification? (Y/N, if Y, please explain) | [ ]  YES[ ]  NOPlease explain, if marked YES:  |
| Explain how customers were notified? Who and when! |  |
| Was there an official visit in connection with this notification?(Y/N, if Y, please explain). | [ ]  YES[ ]  NOPlease explain, if marked YES:  |
| Have any legal actions been taken against the company by authorities? (Y/N, if Y, please explain) | [ ]  YES[ ]  NOPlease explain, if marked YES:  |

|  |  |  |
| --- | --- | --- |
|  | Name of the annex | Number of the annex |
| Customer notification letter and other evidence, please attach  |  |  |
| Explanation of the causes of the product related actions |  |  |
| List the immediate corrections: |  |  |
| List any long-term corrective/preventive actions: |  |  |

***For internal use only***

|  |  |
| --- | --- |
| CASE #  | 0000-000000-0000-00-00 |
| When arrived the notification at the certification body? | \_\_ . \_\_ . 202\_\_ |
| Has the certification body been contacted by the supplier within the specified time frame?  | [ ]  Y [ ]  N *If 'N', a follow-up activity and/or serious nonconformity must be addressed in the subsequent review.* |
| Was the immediate action /corrective action presented appropriate?  | [ ]  Y – immediate action was appropriate (no site visit required). [ ]  Y – immediate action was appropriate, but site visit required. [ ]  N - please explain:[ ]  N/A – please explain:  |
| Is a suspension required at this time? | [ ]  Y - Suspend certificate[ ]  N  |
| Are further measures required? In case further measures are required complete also the purple area | No further measures required [ ] Please explain if further measures are required: |
| Excel list updated:Name/Date:  | [ ]  Y [ ]  N \_\_\_\_\_\_ / \_\_ . \_\_ . 202\_\_ |

|  |  |
| --- | --- |
| Uploaded in IFS database:Name/Date:  | [ ]  Y [ ]  N Add copy of screenshot with notification number |
| Prepared/Completed by:Name:/Date:  | \_\_\_\_\_\_ / \_\_ . \_\_ . 202\_\_ |
| Additional update needed within 10 days? | [ ]  Y[ ]  N |

|  |  |
| --- | --- |
| Information about further actions if needed: |  |

|  |  |
| --- | --- |
| Instruction to the auditor | Check correction / corrective action of the company in next audit:[ ]  Y / [ ]  NFurther instruction to auditor:[ ]  Y / [ ]  NIf Y, which: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

***For the use of auditors***

*Note: This section will not be completed until the next recertification or special audit.*

|  |  |
| --- | --- |
| Date of activity: |  |
| Responsible auditor |  |
| At the next check / audit, the corrective action was maintainedIn each case: | [ ]  Y - The correction / corrective action was appropriate and implemented. [ ]  N Describe your observations.  |
| Has the certification body been contacted by the supplier within the specified time frame?  | [ ]  Y [ ]  N  |
| Any additional notes |  |