

## **HIBC Basic UDI-DI Summary**

The HIBC Basic UDI-DI enables manufacturers to connect and identify devices with the same intended purpose, risk class and essential design and manufacturing characteristics. The HIBC Basic UDI-DI satisfies the Basic UDI-DI requirements in the European Union's Medical Device Regulation (MDR) and In-Vitro Diagnostic Regulation (IVDR). The Basic UDI-DI is required in the EU's EUDAMED database and is referenced in relevant documentation (i.e. certificates and technical documentation).

The HIBC Basic UDI-DI is assigned by the manufacturing following the below guidelines. The HIBC Basic UDI-DI does not appear on any device packaging.

## HIBC Basic UDI-DI Structure

|                                    | Field Length | Format                       | Example           | Description                                                                                                                                                   |
|------------------------------------|--------------|------------------------------|-------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>++</b>                          | 2            | Fixed Length                 | ++                | HIBC Basic UDI-DI Flag Character “++”                                                                                                                         |
| <b>Labeler Identification Code</b> | 4            | Fixed Length Alphanumeric    | A999              | Labeler Identification Code (LIC) an alphanumeric identifier, with the first character always being alphabetic.                                               |
| <b>Model Identifier</b>            | 1-17         | Variable Length Alphanumeric | MODELIDENTIFIER11 | Identifier assigned by the LIC-holder to represent devices with the same intended purpose, risk class, and essential design and manufacturing characteristics |
| <b>Check Character</b>             | 2            | Fixed Length Alphanumeric    | S8                | Calculated using Mod 1021 and Mod 32                                                                                                                          |

Example:

++A999MODELIDENTIFIER11S8

|                         |      |                   |                 |
|-------------------------|------|-------------------|-----------------|
| ++                      | A999 | MODELIDENTIFIER11 | S8              |
| HIBCC Basic UDI-DI Flag | LIC  | Model Identifier  | Check Character |

## HIBCC Basic UDI-DI Check Character Calculation

The HIBCC keying check character scheme utilizes Modulo 1021 arithmetic to calculate the check value and then two characters from a 32-character set to represent the check value. The check value is computed by multiplying the character next to the check character pair by the prime number 2 and then moving to the left, summing the product of the data character value by the next ascending prime number. When the sum is greater than 1021, then 1021 is subtracted from the sum until it is less than 1021. This continues until all the data characters are processed. The resulting number is the Modulo 1021 check character value.

The check character value is encoded using two characters from a depleted alphanumeric set in which the visually similar characters 0, 1, O and I are removed. The resulting 32-character set is assigned values 0 to 31. The Modulo 1021 check character value is encoded as  $A1 * 32 + A2$ , where A1 and A2 are members of the depleted alphanumeric set.

The data character values for the purposes of this checking scheme are from the set shown in Table 1. The 32-character depleted alphanumeric set with their different values is shown in Table 2.

## HIBC Basic UDI-DI Check Character Calculation Example

Check character calculation example, which calculates the keying check characters A1 and A2.

++A999MODELIDENTIFIER11(A1)(A2)

Multiply the character value from Table 1 of the first character next to the check characters, by the first in a sequence of increasing prime numbers, 2, 3, 5, 7, 11, 13, 17, 19, 23, 29, 31, 37, 41, 43, 47, 53, 59, 61, 67, 71, 73, 79 and 83. That character, which is the last character when reading from left to right, is the “1” (One) which is value 14, and is multiplied by the prime number 2. This process continues to the left.

$$14*2 + 14*3 + 46*5 + 33*7 + 37*11 + 34*13 + 37*17 + 48*19 + 42*23 + 33*29 + 32*31 + 37*37 + 40*41 + 33*43 + 32*47 + 43*53 + 41*59 + 22*61 + 22*67 + 22*71 + 29*73 + 8*79 + 8*83$$
$$28 + 42 + 230 + 231 + 407 + 442 + 629 + 912 + 966 + 957 + 992 + 1369 + 1640 +$$
$$1419 + 1504 + 2279 + 2419 + 1342 + 1474 + 1562 + 2117 + 632 + 664$$

Summing the first six values results in a number greater than 1021, i.e.,  $28 + 42 + 230 + 231 + 407 + 442 = 1380$ .  $1380 - 1021 = 359$ . Adding 359 to the next two values,  $359 + 629 + 912 = 1900$ .  $1900 - 1021 = 879$ . Continuing,  $879 + 966 = 1845$ .  $1845 - 1021 = 824$ .  $824 + 957 - 1021 = 760$ .  $760 + 992 - 1021 = 731$ .  $731 + 1369 - 1021 = 1079$ , which is still bigger than 1021, so another subtraction is required.  $1079 - 1021 = 58$ .  $58 + 1640 - 1021 = 677$  which is the partial check value for the first row.

Equivalently, the products can be summed and then divided by 1021. The whole number is discarded (which is the same as subtracting 1021 that number of times) and the remainder is the check value. So, adding 677 to the sum of the bottom row,  $15455 = 16132$ .  $16132 / 1021 = 15$  and  $774/1021$ . The check character value is 774.

This value, 774, is now encoded in two characters from the 32-character set in Table 2 according to  $A1 * 32 + A2$ . So,  $774 / 32 = 24$  and  $24/32$ . Therefore, the check character values are 24, 6, which according to Table 2, are the characters S, 8. Therefore, the entire data string is as follows.

++A999MODELIDENTIFIER11S8

# HIBC Basic UDI-DI



Table 1

| Character | Value |
|-----------|-------|
| !         | 0     |
| "         | 1     |
| %         | 2     |
| &         | 3     |
| '         | 4     |
| (         | 5     |
| )         | 6     |
| *         | 7     |
| +         | 8     |
| ,         | 9     |
| -         | 10    |
| .         | 11    |
| /         | 12    |
| 0         | 13    |
| 1         | 14    |
| 2         | 15    |
| 3         | 16    |
| 4         | 17    |
| 5         | 18    |
| 6         | 19    |
| 7         | 20    |
| 8         | 21    |
| 9         | 22    |
| :         | 23    |
| ;         | 24    |
| <         | 25    |
| =         | 26    |
| >         | 27    |
| ?         | 28    |
| A         | 29    |
| B         | 30    |
| C         | 31    |
| D         | 32    |
| E         | 33    |
| F         | 34    |
| G         | 35    |
| H         | 36    |
| I         | 37    |
| J         | 38    |
| K         | 39    |
| L         | 40    |

| Character | Value |
|-----------|-------|
| M         | 41    |
| N         | 42    |
| O         | 43    |
| P         | 44    |
| Q         | 45    |
| R         | 46    |
| S         | 47    |
| T         | 48    |
| U         | 49    |
| V         | 50    |
| W         | 51    |
| X         | 52    |
| Y         | 53    |
| Z         | 54    |
| _         | 55    |
| a         | 56    |
| b         | 57    |
| c         | 58    |
| d         | 59    |
| e         | 60    |
| f         | 61    |
| g         | 62    |
| h         | 63    |
| i         | 64    |
| j         | 65    |
| k         | 66    |
| l         | 67    |
| m         | 68    |
| n         | 69    |
| o         | 70    |
| p         | 71    |
| q         | 72    |
| r         | 73    |
| s         | 74    |
| t         | 75    |
| u         | 76    |
| v         | 77    |
| w         | 78    |
| x         | 79    |
| y         | 80    |
| z         | 81    |

# HIBC Basic UDI-DI



Table 2

| Character |           | Value |
|-----------|-----------|-------|
| 2         | Two       | 0     |
| 3         | Three     | 1     |
| 4         | Four      | 2     |
| 5         | Five      | 3     |
| 6         | Six       | 4     |
| 7         | Seven     | 5     |
| 8         | Eight     | 6     |
| 9         | Nine      | 7     |
| A         | Capital A | 8     |
| B         | Capital B | 9     |
| C         | Capital C | 10    |
| D         | Capital D | 11    |
| E         | Capital E | 12    |
| F         | Capital F | 13    |
| G         | Capital G | 14    |
| H         | Capital H | 15    |

| Character |           | Value |
|-----------|-----------|-------|
| J         | Capital J | 16    |
| K         | Capital K | 17    |
| L         | Capital L | 18    |
| M         | Capital M | 19    |
| N         | Capital N | 20    |
| P         | Capital P | 21    |
| Q         | Capital Q | 22    |
| R         | Capital R | 23    |
| S         | Capital S | 24    |
| T         | Capital T | 25    |
| U         | Capital U | 26    |
| V         | Capital V | 27    |
| W         | Capital W | 28    |
| X         | Capital X | 29    |
| Y         | Capital Y | 30    |
| Z         | Capital Z | 31    |